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(54) **SPINAL CORD STIMULATOR SYSTEM**

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(58) **Field of Classification Search**

CPC A61N 1/36071; A61N 1/36185; A61N 1/36157; A61N 1/025; A61N 1/0553

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,195,540 A	7/1965	Waller
3,718,134 A	2/1973	Brindley

(Continued)

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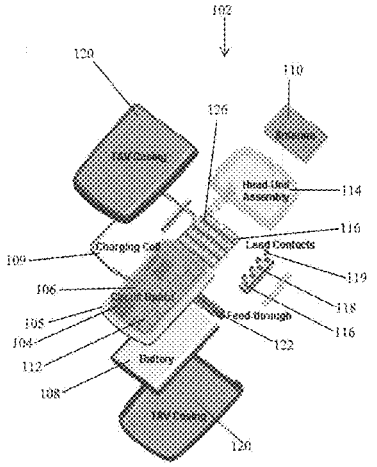
(57) **ABSTRACT**

Spinal cord stimulation (SCS) system having a recharging system with self-alignment, a system for mapping current fields using a completely wireless system, multiple independent electrode stimulation outsource, and IPG control through software on Smartphone/mobile device and tablet hardware during trial and permanent implants. SCS system can include multiple electrodes, multiple, independently programmable, stimulation channels within an implantable pulse generator (IPG) providing concurrent, but unique stimulation fields. SCS system can include a replenishable power source, rechargeable using transcutaneous power transmissions between antenna coil pairs. An external charger unit, having its own rechargeable battery, can charge the IPG replenishable power source. A real-time clock can provide an auto-run schedule for daily stimulation. A bi-directional telemetry link informs the patient or clinician the status of the system, including the state of charge of the IPG battery. Other processing circuitry in current IPG allows electrode impedance measurements to be made.

20 Claims, 11 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,724,467	A	4/1973	Avery et al.
3,727,616	A	4/1973	Lenzkes
3,822,708	A	7/1974	Zilber
3,867,950	A	2/1975	Fischell
3,888,260	A	6/1975	Fischell
3,942,535	A	3/1976	Schulman
4,014,346	A	3/1977	Brownlee et al.
4,019,518	A	4/1977	Maurer et al.
4,082,097	A	4/1978	Mann et al.
4,134,408	A	1/1979	Brownlee et al.
4,232,679	A	11/1980	Schulman
4,379,462	A	4/1983	Borkan et al.
4,390,023	A	6/1983	Rise
4,408,608	A	10/1983	Daly et al.
4,459,989	A	7/1984	Borkan
4,510,936	A	4/1985	Fourcin et al.
4,512,351	A	4/1985	Pohndorf
4,541,432	A	9/1985	Molina-Negro et al.
4,549,556	A	10/1985	Tarjan et al.
4,608,986	A	9/1986	Beranek et al.
4,640,286	A	2/1987	Thomson
4,690,145	A	9/1987	King-Smith et al.
4,712,558	A	12/1987	Kidd et al.
5,036,850	A	8/1991	Owens
5,119,832	A	6/1992	Xavier
5,143,067	A	9/1992	Rise et al.
5,255,691	A	10/1993	Otten
5,279,292	A	1/1994	Baumann et al.
5,314,457	A	5/1994	Jeutter et al.
5,354,320	A	10/1994	Schaldach et al.
5,374,285	A	12/1994	Vaiani et al.
5,391,193	A	2/1995	Thompson
5,411,537	A	5/1995	Munshi et al.
5,417,719	A	5/1995	Hull et al.
5,441,527	A	8/1995	Erickson et al.
5,443,486	A	8/1995	Hrdlicka et al.
5,458,629	A	10/1995	Baudino et al.
5,458,631	A	10/1995	Xavier
5,501,703	A	3/1996	Holsheimer et al.
5,591,217	A	1/1997	Barreras
5,630,835	A	5/1997	Brownlee
5,643,330	A	7/1997	Holsheimer et al.
5,662,689	A	9/1997	Elsberry et al.
5,690,693	A	11/1997	Wang et al.
5,702,431	A	12/1997	Wang et al.
5,713,939	A	2/1998	Nedungadi et al.
5,733,313	A	3/1998	Barreras et al.
5,733,322	A	3/1998	Starkebaum
5,769,877	A	6/1998	Barreras, Sr.
5,843,146	A	12/1998	Cross, Jr.
5,861,019	A	1/1999	Sun et al.
5,865,843	A	2/1999	Baudino
5,893,883	A	4/1999	Torgerson et al.
5,895,416	A	4/1999	Barreras et al.
5,913,882	A	6/1999	King
5,935,159	A	8/1999	Cross, Jr. et al.
5,938,690	A	8/1999	Law et al.
6,009,350	A	12/1999	Renken
6,052,623	A	4/2000	Fenner et al.
6,052,624	A	4/2000	Mann
6,120,502	A	9/2000	Michelson
6,167,312	A	12/2000	Goedeke
6,169,925	B1	1/2001	Villaseca et al.
6,175,769	B1	1/2001	Errico et al.
6,181,969	B1	1/2001	Gord
6,181,971	B1	1/2001	Doan
6,185,452	B1	2/2001	Schulman et al.
6,185,463	B1	2/2001	Baudino
6,205,361	B1	3/2001	Kuzma et al.
6,208,894	B1	3/2001	Schulman et al.
6,216,045	B1	4/2001	Black et al.
6,227,204	B1	5/2001	Baumann et al.
6,236,892	B1	5/2001	Feler
6,240,317	B1	5/2001	Villaseca et al.
6,240,318	B1	5/2001	Philips
6,249,705	B1	6/2001	Snell
6,249,707	B1	6/2001	Kohnen et al.
6,266,564	B1	7/2001	Hill et al.
6,309,401	B1	10/2001	Redko et al.
6,379,300	B1	4/2002	Haubrich
6,381,496	B1	4/2002	Meadows et al.
6,393,325	B1	5/2002	Mann et al.
6,415,187	B1	7/2002	Kuzma et al.
6,456,256	B1	9/2002	Amundson et al.
6,456,887	B1	9/2002	Dudding et al.
6,463,329	B1	10/2002	Goedeke
6,473,653	B1	10/2002	Schallhorn et al.
6,477,424	B1	11/2002	Thompson et al.
6,505,072	B1	1/2003	Linder et al.
6,505,401	B1	1/2003	Doan
6,516,227	B1	2/2003	Meadows et al.
6,522,932	B1	2/2003	Kuzma et al.
6,535,766	B1	3/2003	Thompson et al.
6,539,253	B2	3/2003	Thompson et al.
6,553,263	B1	4/2003	Meadows et al.
6,553,264	B2	4/2003	Redko et al.
6,587,724	B2	7/2003	Mann
6,600,954	B2	7/2003	Cohen et al.
6,609,031	B1	8/2003	Law et al.
6,609,032	B1	8/2003	Woods et al.
6,614,406	B2	9/2003	Amundson et al.
6,622,048	B1	9/2003	Mann et al.
6,650,944	B2	11/2003	Goedeke et al.
6,654,642	B2	11/2003	North et al.
6,658,297	B2	12/2003	Loeb
6,658,302	B1	12/2003	Kuzma et al.
6,662,052	B1	12/2003	Sarwal et al.
6,662,053	B2	12/2003	Borkan
6,664,763	B2	12/2003	Echarri et al.
6,671,544	B2	12/2003	Baudino
6,675,045	B2	1/2004	Mass et al.
6,675,046	B2	1/2004	Holsheimer
6,708,065	B2	3/2004	Von Arx et al.
6,741,892	B1	5/2004	Meadows et al.
6,745,079	B2	6/2004	King
6,757,970	B1	7/2004	Kuzma et al.
6,795,737	B2	9/2004	Gielen et al.
6,809,701	B2	10/2004	Amundson et al.
6,819,958	B2	11/2004	Weiner et al.
6,847,849	B2	1/2005	Mamo et al.
6,850,802	B2	2/2005	Holsheimer
6,868,288	B2	3/2005	Thompson
6,871,099	B1	3/2005	Whitehurst et al.
6,889,086	B2	5/2005	Mass et al.
6,892,097	B2	5/2005	Holsheimer
6,895,280	B2	5/2005	Meadows et al.
6,895,283	B2	5/2005	Erickson et al.
6,901,292	B2	5/2005	Hrdlicka et al.
6,909,917	B2	6/2005	Woods et al.
6,920,359	B2	7/2005	Meadows et al.
6,930,602	B2	8/2005	Dublin et al.
6,937,891	B2	8/2005	Leinders et al.
6,941,171	B2	9/2005	Mann et al.
6,950,706	B2	9/2005	Rodriguez et al.
6,950,709	B2	9/2005	Baudino
6,981,314	B2	1/2006	Black et al.
6,985,088	B2	1/2006	Goetz et al.
6,993,384	B2	1/2006	Bradley
7,009,313	B1	3/2006	Parramon et al.
7,016,733	B2	3/2006	Dublin et al.
7,023,359	B2	4/2006	Goetz et al.
7,024,246	B2	4/2006	Acosta et al.
7,035,690	B2	4/2006	Goetz
7,039,470	B1	5/2006	Wessman
7,047,076	B1	5/2006	Li et al.
7,047,081	B2	5/2006	Kuzma
7,047,082	B1	5/2006	Schrom et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,047,627 B2 5/2006 Black et al.
7,051,419 B2 5/2006 Schrom et al.
7,076,304 B2 7/2006 Thompson
7,099,718 B1 8/2006 Thacker et al.
7,107,102 B2 9/2006 Daignault, Jr. et al.
7,110,824 B2 9/2006 Amundson et al.
7,127,296 B2 10/2006 Bradley
7,127,297 B2 10/2006 Law et al.
7,127,298 B1 10/2006 He et al.
7,142,909 B2 11/2006 Greenberg et al.
7,146,223 B1 12/2006 King
7,162,306 B2 1/2007 Caby et al.
7,174,215 B2 2/2007 Bradley
7,177,690 B2 2/2007 Woods et al.
7,177,691 B2 2/2007 Meadows et al.
7,177,702 B2 2/2007 Wallace et al.
7,181,286 B2 2/2007 Sieracki et al.
7,184,836 B1 2/2007 Meadows et al.
7,187,978 B2 3/2007 Malek et al.
7,206,642 B2 4/2007 Pardo et al.
7,211,103 B2 5/2007 Greenberg et al.
7,212,133 B2 5/2007 Goetz et al.
7,215,991 B2 5/2007 Besson et al.
7,225,032 B2 5/2007 Schmeling et al.
7,239,918 B2 7/2007 Strother et al.
7,239,920 B1 7/2007 Thacker et al.
7,248,929 B2 7/2007 Meadows et al.
7,254,443 B2 8/2007 Jelen et al.
7,254,445 B2 8/2007 Law et al.
7,254,446 B1 8/2007 Erickson et al.
7,263,406 B2 8/2007 Toy et al.
7,295,876 B1 11/2007 Erickson
7,295,878 B1 11/2007 Meadows et al.
7,310,873 B2 12/2007 Pardo et al.
7,317,948 B1 1/2008 King et al.
7,324,852 B2 1/2008 Barolat et al.
7,337,003 B2 2/2008 Malinowski
7,359,751 B1 4/2008 Erickson et al.
7,359,755 B2 4/2008 Jones et al.
7,363,079 B1 4/2008 Thacker et al.
7,369,897 B2 5/2008 Boveja et al.
7,376,466 B2 5/2008 He et al.
7,389,146 B2 6/2008 Hanson et al.
7,389,147 B2 6/2008 Wahlstrand et al.
7,428,438 B2 9/2008 Parramon et al.
7,437,193 B2 10/2008 Parramon et al.
7,437,197 B2 10/2008 Harris et al.
7,444,181 B2 10/2008 Shi et al.
7,444,184 B2 10/2008 Boveja et al.
7,463,927 B1 12/2008 Chaouat
7,471,986 B2 12/2008 Hatlestad
7,483,752 B2 1/2009 Von Arx et al.
7,489,966 B2 2/2009 Leinders et al.
7,496,404 B2 2/2009 Meadows et al.
7,499,755 B2 3/2009 Cross, Jr.
7,515,968 B2 4/2009 Metzler et al.
7,519,432 B2 4/2009 Bolea et al.
7,526,341 B2 4/2009 Goetz et al.
7,539,538 B2 5/2009 Parramon et al.
7,546,164 B2 6/2009 King
7,548,788 B2 6/2009 Chinn et al.
7,551,963 B2 6/2009 Rusin et al.
7,555,346 B1 6/2009 Woods et al.
7,571,001 B2 8/2009 Thacker et al.
7,580,753 B2 8/2009 Kim et al.
7,603,179 B1 10/2009 Grandhe
7,613,518 B2 11/2009 Qin et al.
7,617,006 B2 11/2009 Metzler et al.
7,630,749 B2 12/2009 Squeri
7,647,121 B2 1/2010 Wahlstrand et al.
7,650,192 B2 1/2010 Wahlstrand
7,657,319 B2 2/2010 Goetz et al.
7,658,196 B2 2/2010 Ferreri et al.
7,672,734 B2 3/2010 Anderson et al.
7,684,869 B2 3/2010 Bradley et al.
7,684,873 B2 3/2010 Gerber
7,697,995 B2 4/2010 Cross, Jr. et al.
7,706,888 B2 4/2010 Jolly
7,715,912 B2 5/2010 Rezai et al.
7,715,924 B2 5/2010 Rezai et al.
7,725,196 B2 5/2010 Machado et al.
7,729,781 B2 6/2010 Swoyer et al.
7,734,340 B2 6/2010 De Ridder
7,734,342 B2 6/2010 Gielen et al.
7,738,963 B2 6/2010 Hickman et al.
7,738,966 B2 6/2010 Skubitz et al.
7,742,810 B2 6/2010 Moffitt et al.
7,742,821 B1 6/2010 Vamos et al.
7,747,330 B2 6/2010 Nolan et al.
7,761,167 B2 7/2010 Bennett et al.
7,761,170 B2 7/2010 Kaplan et al.
7,761,985 B2 7/2010 Hegland et al.
7,765,005 B2 7/2010 Stevenson
7,765,011 B2 7/2010 Skubitz et al.
7,769,462 B2 8/2010 Meadows et al.
7,787,960 B2 8/2010 Lubenow et al.
7,797,048 B2 9/2010 Stevenson et al.
7,797,054 B2 9/2010 Skubitz et al.
7,797,057 B2 9/2010 Harris
7,801,600 B1 9/2010 Carbunaru et al.
7,801,602 B2 9/2010 McClure et al.
7,801,615 B2 9/2010 Meadows et al.
7,801,621 B1 9/2010 Thacker et al.
7,803,021 B1 9/2010 Brase
7,805,189 B2 9/2010 Stein et al.
7,805,197 B2 9/2010 Bradley
7,813,796 B2 10/2010 Greenberg et al.
7,813,803 B2 10/2010 Heruth et al.
7,813,809 B2 10/2010 Strother et al.
7,818,068 B2 10/2010 Meadows et al.
7,831,306 B2 11/2010 Finch et al.
7,831,311 B2 11/2010 Cross, Jr. et al.
7,831,313 B2 11/2010 Lauro
7,835,795 B2 11/2010 Alexander et al.
7,844,343 B2 11/2010 Wahlstrand et al.
7,848,817 B2 12/2010 Janzig et al.
7,848,818 B2 12/2010 Barolat et al.
7,848,819 B2 12/2010 Goetz et al.
7,848,820 B2 12/2010 Abrahamson
7,853,330 B2 12/2010 Bradley et al.
7,856,277 B1 12/2010 Thacker et al.
7,860,568 B2 12/2010 Deininger et al.
7,860,570 B2 12/2010 Whitehurst et al.
7,872,884 B2 1/2011 Parramon et al.
7,881,796 B2 2/2011 Scott et al.
7,881,805 B2 2/2011 Bradley et al.
7,885,712 B2 2/2011 Goetz et al.
7,891,085 B1 2/2011 Kuzma et al.
7,899,542 B2 3/2011 Cowan et al.
7,904,148 B2 3/2011 Greenberg et al.
7,908,013 B2 3/2011 Miesel et al.
7,930,030 B2 4/2011 Woods et al.
7,930,037 B2 4/2011 Heruth et al.
7,930,039 B2 4/2011 Olson
7,933,656 B2 4/2011 Sieracki et al.
7,937,158 B2 5/2011 Erickson et al.
7,941,227 B2 5/2011 Barker
7,949,393 B2 5/2011 Varrichio et al.
7,957,797 B2 6/2011 Bourget et al.
7,957,809 B2 6/2011 Bourget et al.
7,957,814 B2 6/2011 Goetz et al.
7,970,003 B2 6/2011 Holt
7,974,703 B2 7/2011 Goetz et al.
7,974,705 B2 7/2011 Zdeblick et al.
7,979,126 B2 7/2011 Payne et al.
7,979,131 B2 7/2011 Feler et al.
7,979,133 B2 7/2011 Feler et al.
7,983,757 B2 7/2011 Miyazawa et al.
7,983,762 B2 7/2011 Gliner et al.
7,983,766 B1 7/2011 Thacker et al.
7,987,000 B2 7/2011 Moffitt et al.
7,991,482 B2 8/2011 Bradley
7,996,091 B2 8/2011 Harris
8,000,794 B2 8/2011 Lozano

(56) **References Cited**

U.S. PATENT DOCUMENTS

8,000,800	B2	8/2011	Takeda et al.
8,005,547	B2	8/2011	Forsberg et al.
RE42,682	E	9/2011	Barreras et al.
8,019,427	B2	9/2011	Moffitt
8,019,438	B2	9/2011	Johnson et al.
8,019,439	B2	9/2011	Kuzma et al.
8,019,440	B2	9/2011	Kokones et al.
8,019,443	B2	9/2011	Schleicher et al.
8,032,224	B2	10/2011	Miesel et al.
8,036,737	B2	10/2011	Goetz et al.
8,036,747	B2	10/2011	Thacker et al.
8,036,754	B2	10/2011	Lee et al.
8,044,635	B2	10/2011	Peterson
8,046,073	B1	10/2011	Pianca
8,050,769	B2	11/2011	Gharib et al.
8,055,337	B2	11/2011	Moffitt et al.
8,065,013	B2	11/2011	Bradley et al.
8,073,542	B2	12/2011	Doerr
8,082,034	B2	12/2011	Keacher
8,082,039	B2	12/2011	Kim et al.
8,086,317	B2	12/2011	Finch et al.
8,086,318	B2	12/2011	Strother et al.
8,108,048	B2	1/2012	Masoud
8,108,049	B2	1/2012	King
8,108,051	B2	1/2012	Cross, Jr. et al.
8,108,052	B2	1/2012	Boling
8,116,880	B2	2/2012	Cross, Jr.
8,121,697	B2	2/2012	Greenberg et al.
8,121,701	B2	2/2012	Woods et al.
8,121,702	B2	2/2012	King
8,126,567	B2	2/2012	Gerber et al.
8,131,358	B2	3/2012	Moffitt et al.
8,135,477	B2	3/2012	Fattouh et al.
8,140,168	B2	3/2012	Olson et al.
8,150,530	B2	4/2012	Wesselink
8,150,533	B2	4/2012	Wessman
8,155,750	B2	4/2012	Jaax et al.
8,155,752	B2	4/2012	Aghassian et al.
8,165,678	B2	4/2012	Forsberg et al.
8,170,674	B2	5/2012	Pyles et al.
8,170,675	B2	5/2012	Alataris et al.
8,175,719	B2	5/2012	Shi et al.
8,175,720	B2	5/2012	Skelton et al.
8,180,445	B1	5/2012	Moffitt
8,180,451	B2	5/2012	Hickman et al.
8,180,462	B2	5/2012	Inman et al.
8,185,207	B2	5/2012	Molnar et al.
8,185,212	B2	5/2012	Carbunaru et al.
8,195,297	B2	6/2012	Penner
8,195,304	B2	6/2012	Strother et al.
8,204,595	B2	6/2012	Pianca et al.
8,209,014	B2	6/2012	Doerr
8,209,021	B2	6/2012	Alataris et al.
8,214,051	B2	7/2012	Sieracki et al.
8,214,057	B2	7/2012	Barolat
8,224,453	B2	7/2012	De Ridder
8,285,388	B2	10/2012	Wahlstrand
2009/0270935	A1	10/2009	Zhao et al.
2011/0184486	A1	7/2011	De Ridder

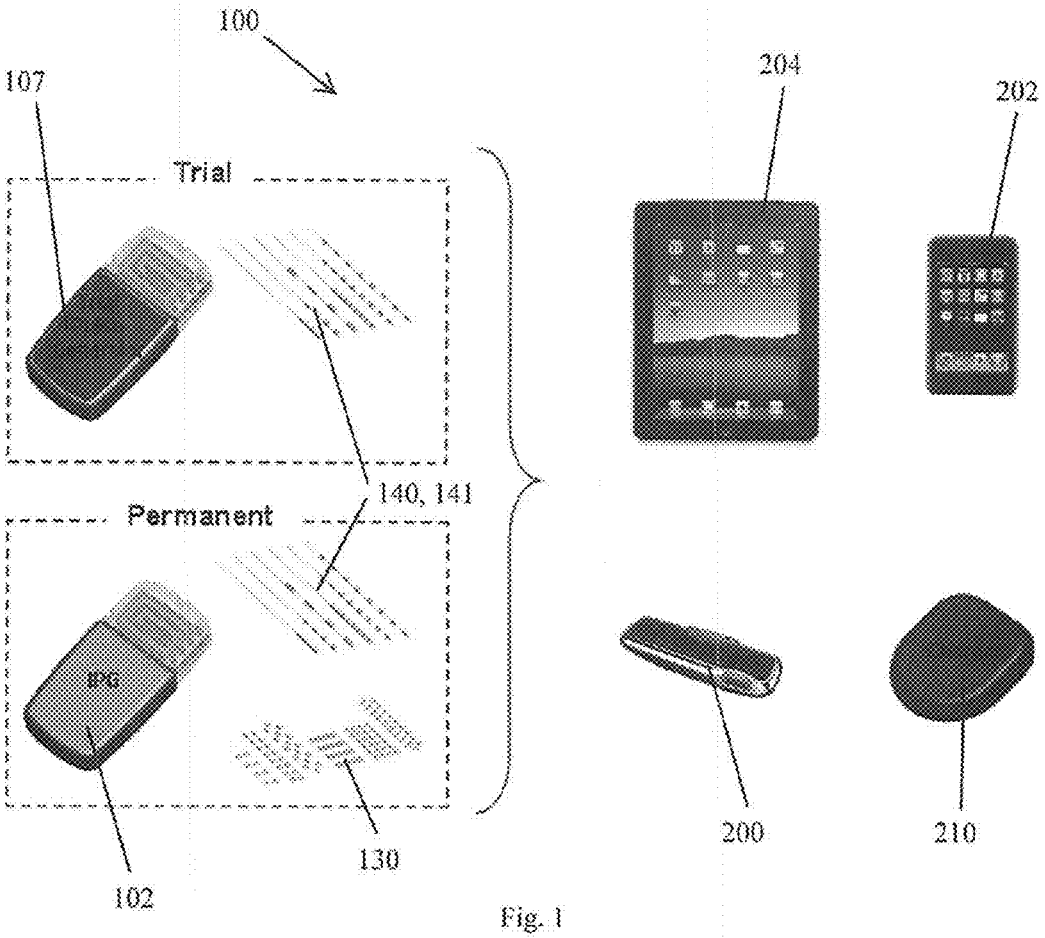
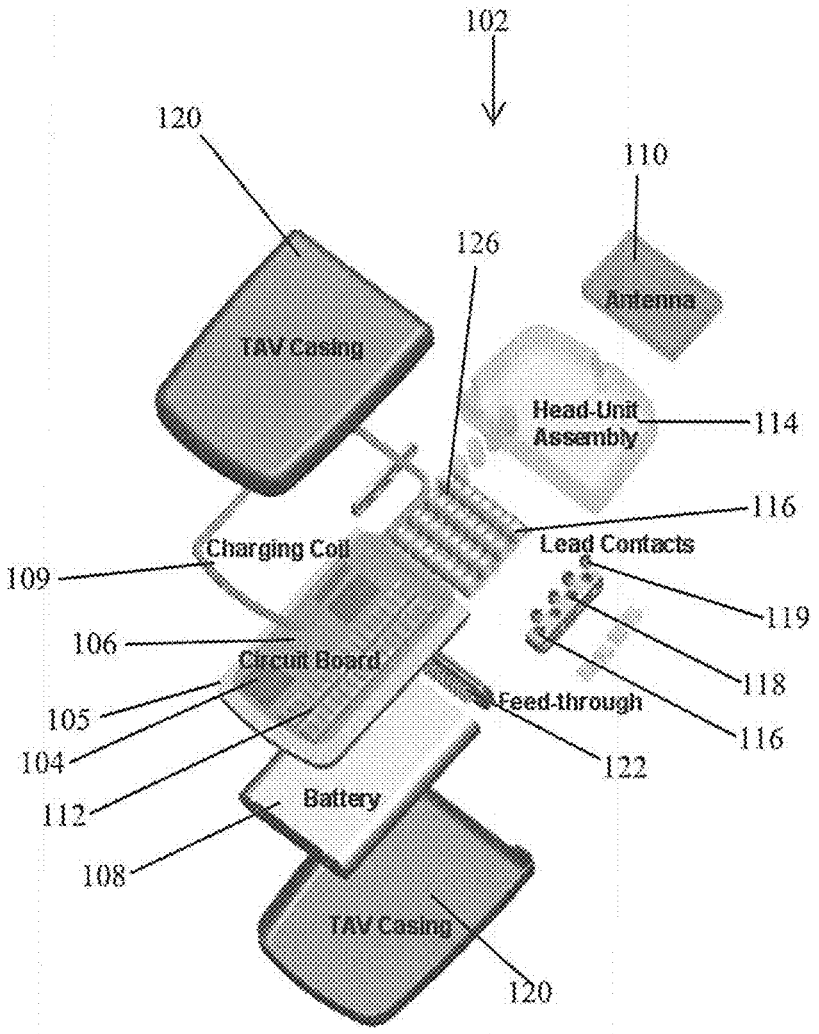


Fig. 1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119
106
Circuit Board
118
105
Feed-through
116
104
122
112
Battery
108
TAV Casing
120

Fig. 2

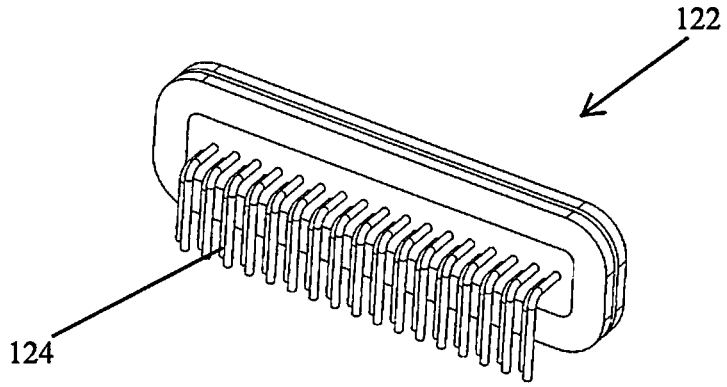


Fig. 3

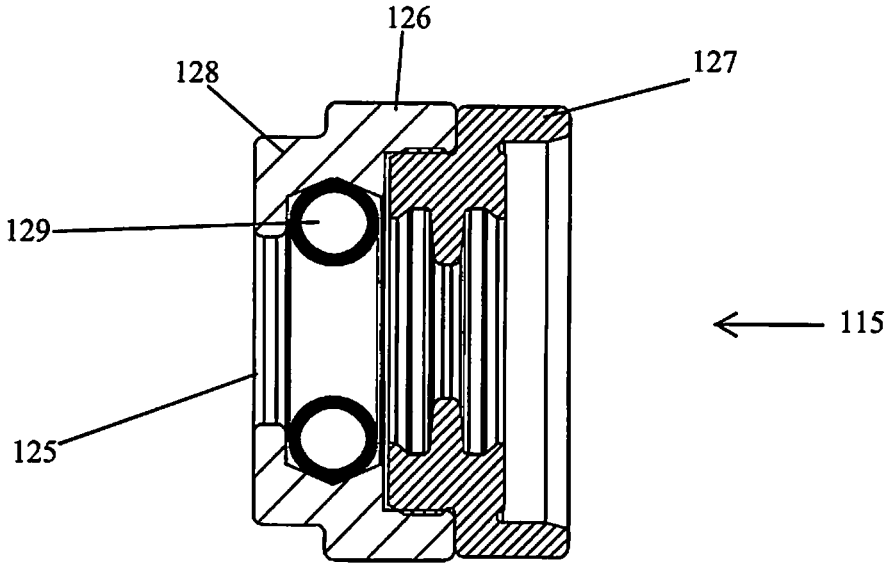


Fig. 4

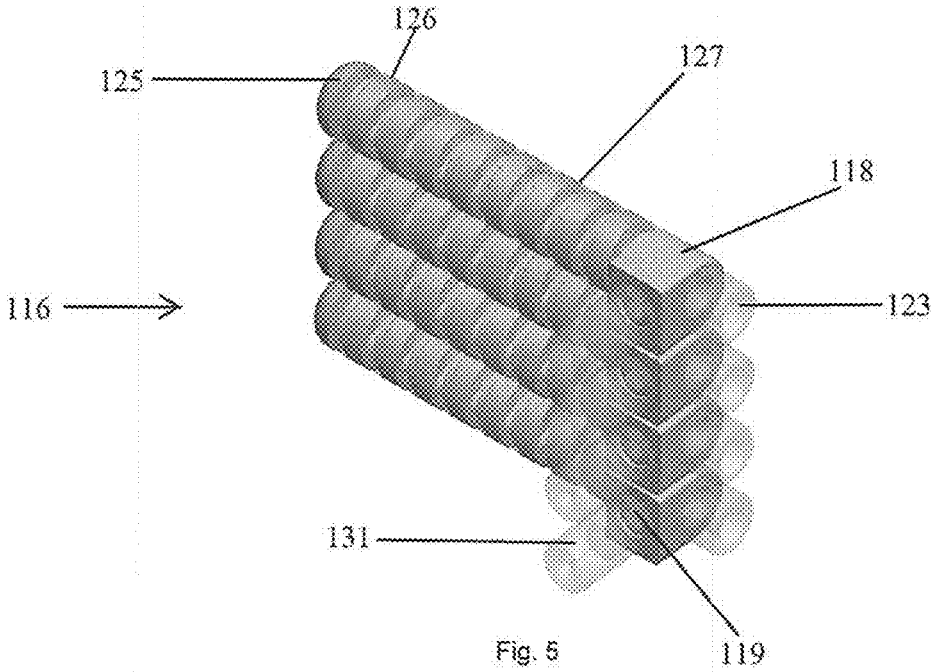

126
125
127
118
116
123
131
119

Fig. 5

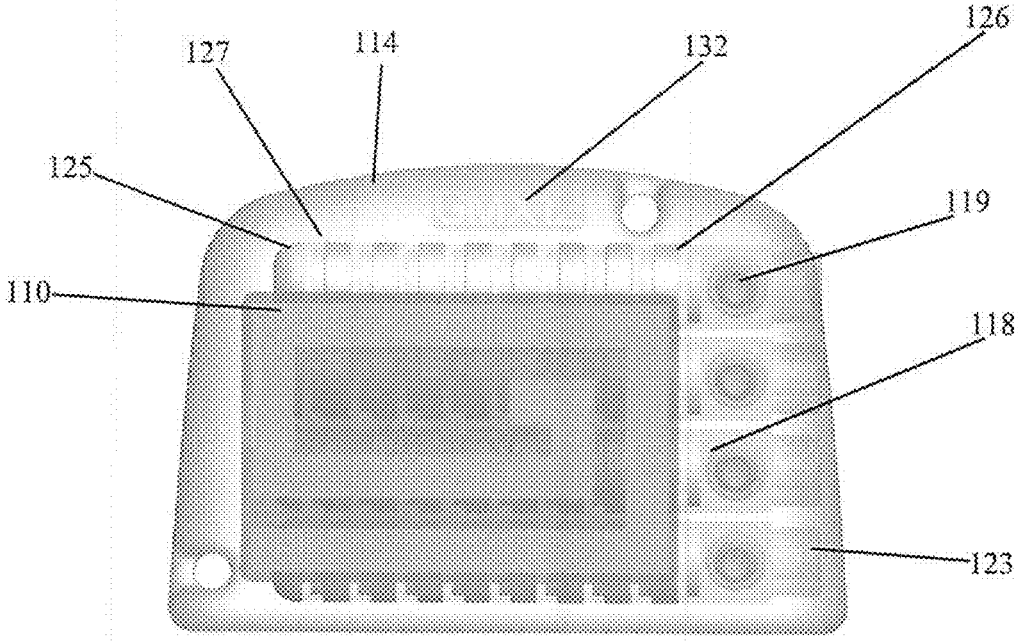

127
114
132
126
125
119
110
118
123

Fig. 6

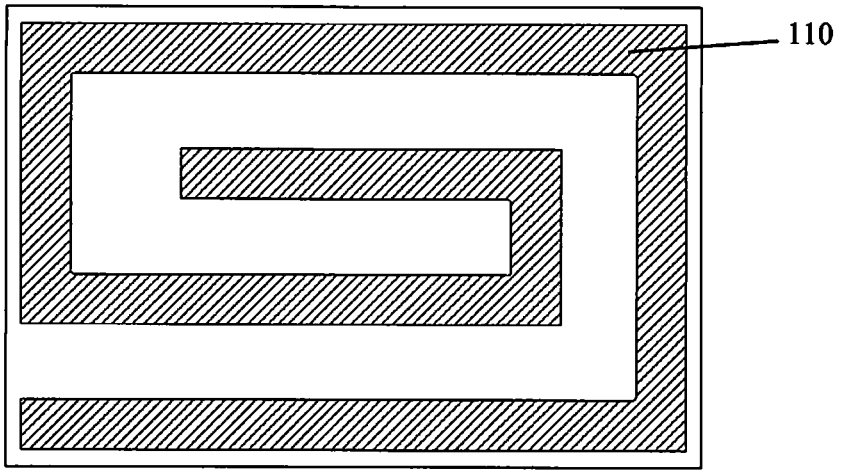


Fig. 7

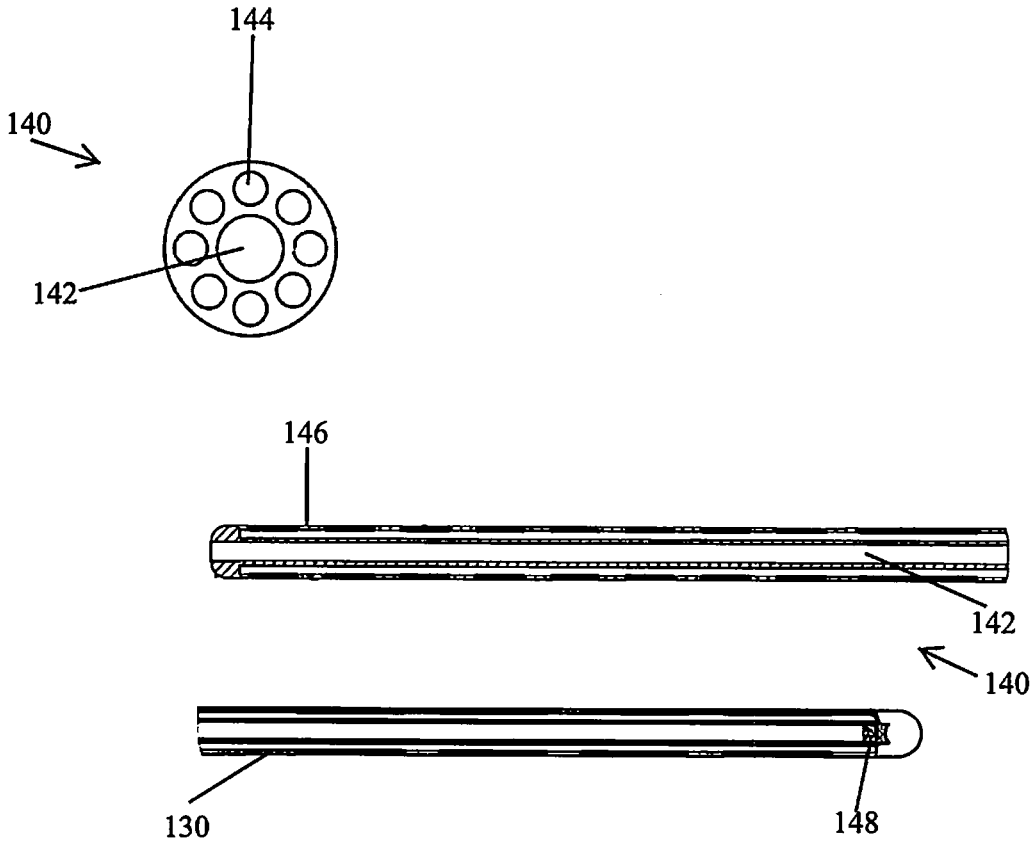


Fig. 8

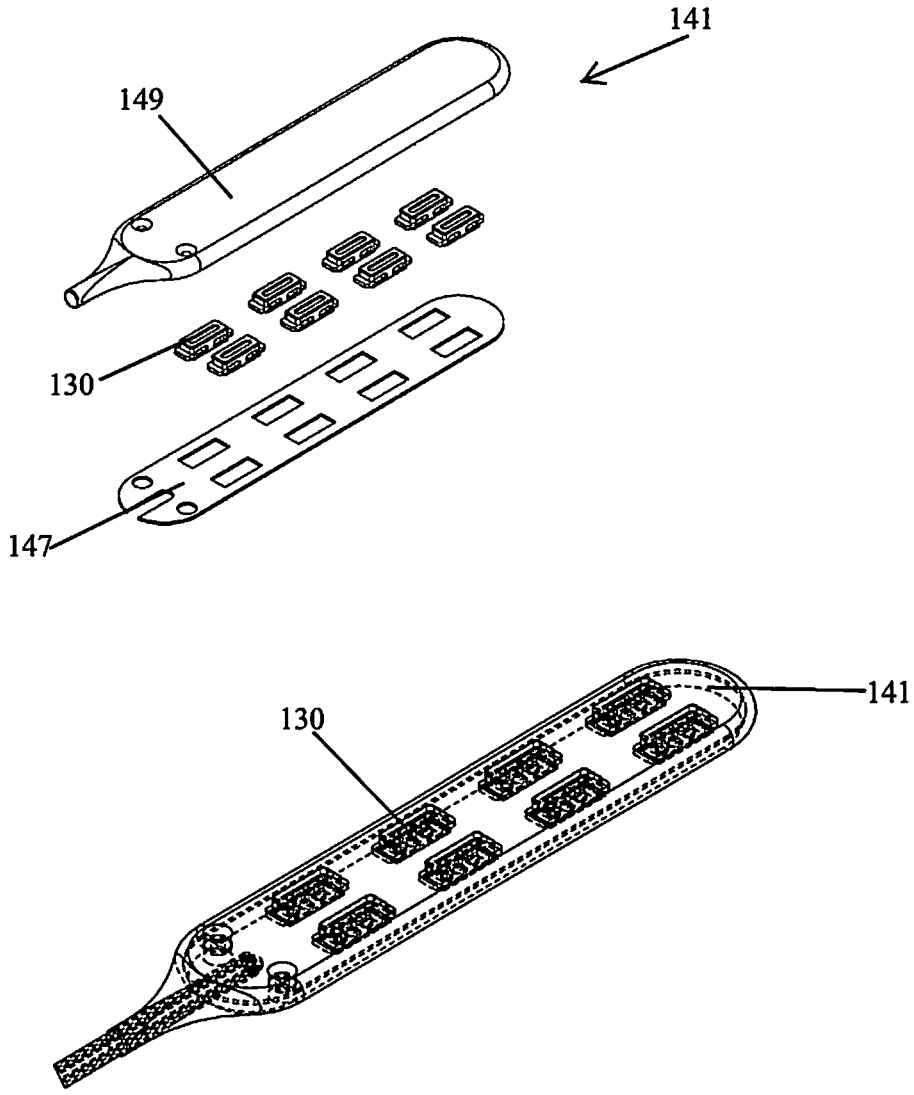


Fig. 9

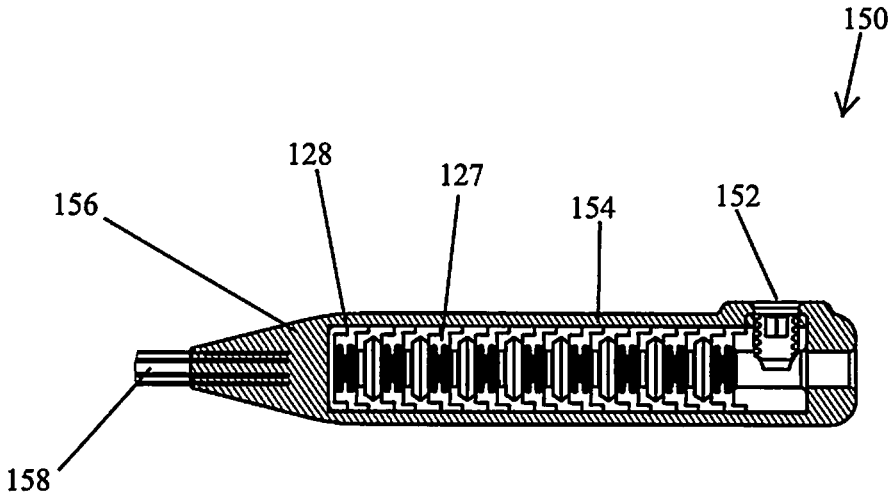


Fig. 10

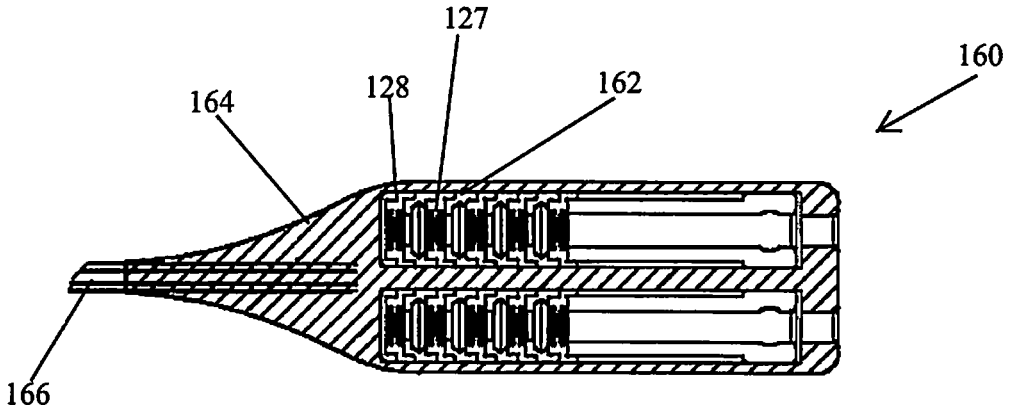


Fig. 11

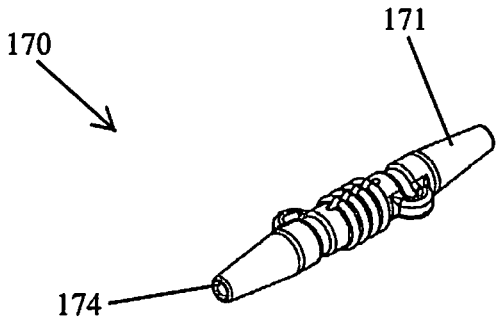


Fig. 12

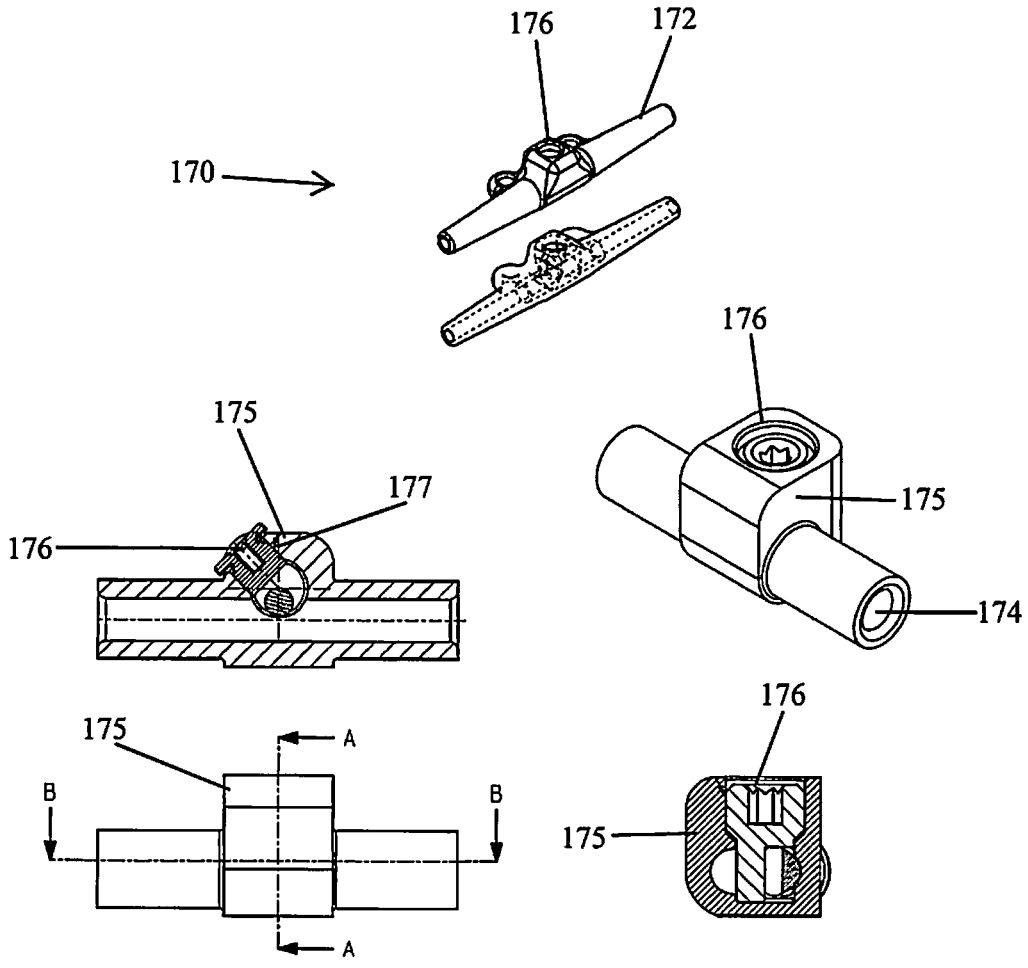


Fig. 13

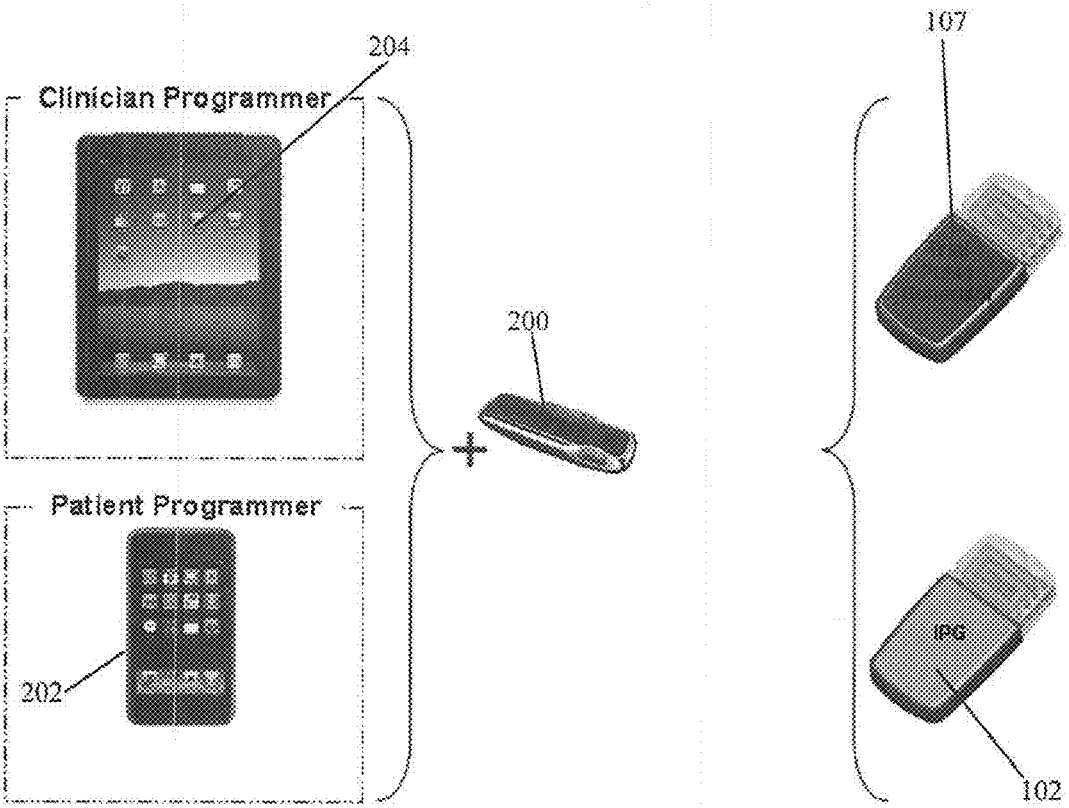
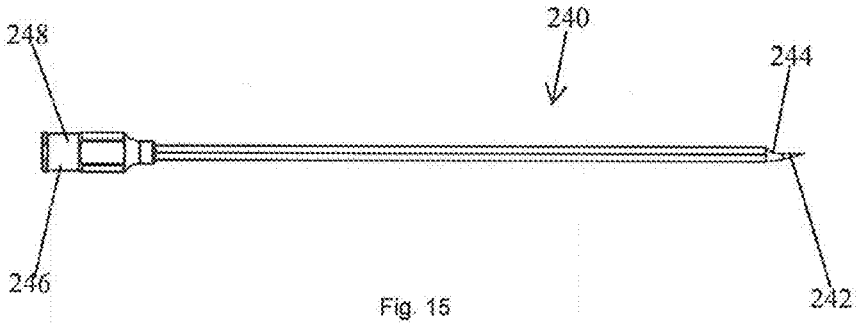

Clinician Programmer
204
200
Patient Programmer
202
107
IPG
102

Fig. 14


248
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244
246
242

Fig. 15

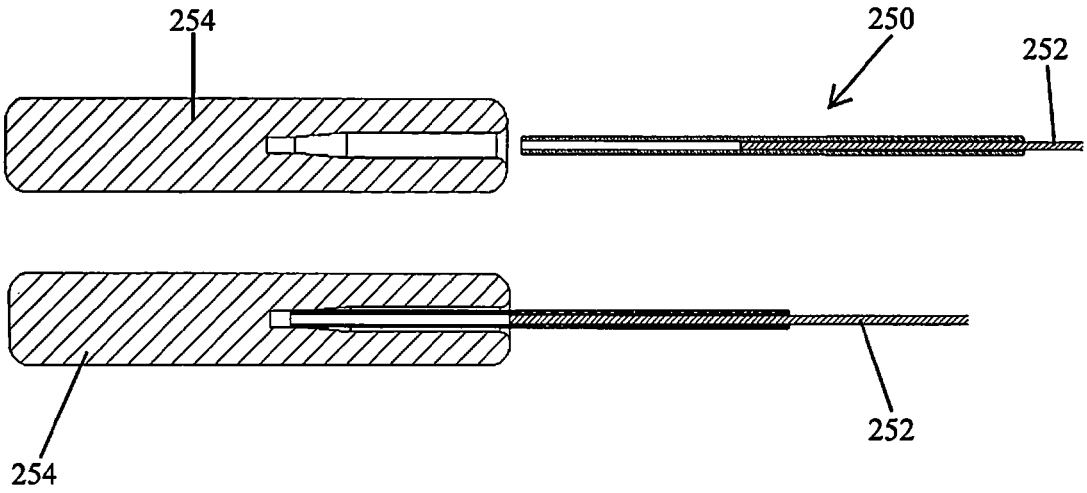

Fig. 16

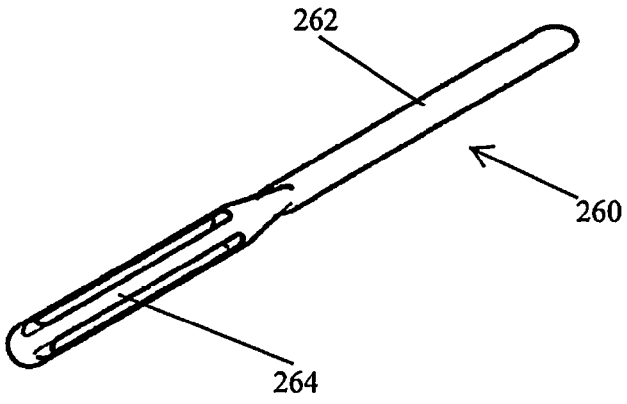

Fig. 17

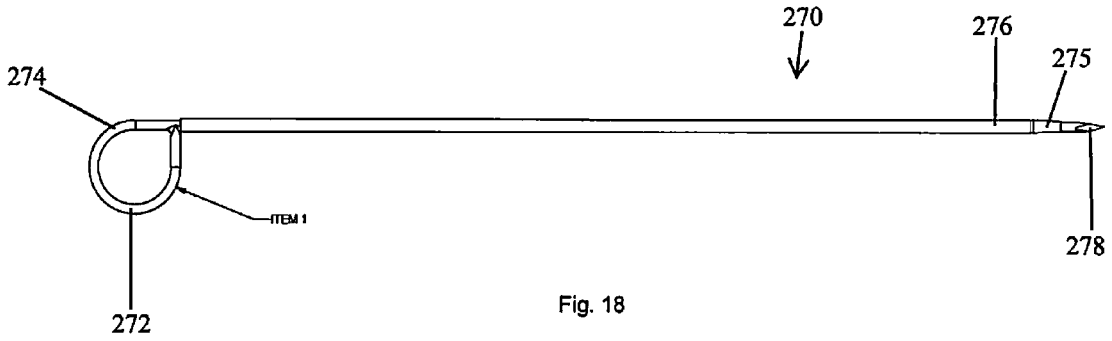

Fig. 18

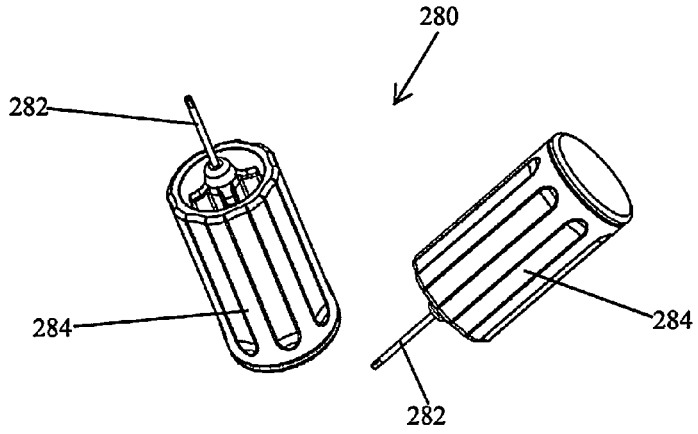

Fig. 19

SPINAL CORD STIMULATOR SYSTEM

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/213,315, now U.S. Pat. No. 9,101,768, filed on Mar. 14, 2014, which claims priority to provisional application No. 61/792,654, filed Mar. 15, 2013.

TECHNICAL FIELD

This disclosure relates to stimulators using electrical pulses in a medical context, and more particularly, applying electrical pulse stimulators to the spinal cord to control pain.

BACKGROUND

A Spinal Cord Stimulator (SCS) is used to exert pulsed electrical signals to the spinal cord to control chronic pain. Spinal cord stimulation, in its simplest form, comprises stimulating electrodes implanted in the epidural space, an electrical pulse generator implanted in the lower abdominal area or gluteal region, conducting wires connecting the electrodes to the electrical pulse generator, an electrical pulse generator remote control, and an electrical pulse generator charger. Spinal cord stimulation has notable analgesic properties and, at the present, is used mostly in the treatment of failed back surgery syndrome, complex regional pain syndrome and refractory pain due to ischemia.

Electrotherapy of pain by neurostimulation began shortly after Melzack and Wall proposed the gate control theory in 1965. This theory proposed that nerves carrying painful peripheral stimuli and nerves carrying touch and vibratory sensation both terminate in the dorsal horn (the gate) of the spinal cord. It was hypothesized that input to the dorsal horn of the spinal cord could be manipulated to "close the gate" to the nerves. As an application of the gate control theory, Shealy et al. implanted the first spinal cord stimulator device directly on the dorsal column for the treatment of chronic pain in 1971.

Spinal cord stimulation does not eliminate pain. The electrical impulses from the stimulator override the pain messages so that the patient does not feel the pain intensely. In essence, the stimulator masks the pain. A trial implantation is performed before implanting the permanent stimulator. The physician first implants a trial stimulator through the skin (percutaneously) to perform stimulations as a trial run. Because a percutaneous trial stimulator tends to move from its original location, it is considered temporary. If the trial is successful, the physician can then implant a permanent stimulator. The permanent stimulator is implanted under the skin of the abdomen with the leads inserted under the skin and subcutaneously fed to and inserted into the spinal canal. This placement of the stimulator in the abdomen is a more stable, effective location. The leads, which consist of an array of electrodes, can be percutaneous type or paddle type. Percutaneous electrodes are easier to insert in comparison with paddle type, which are inserted via incision over spinal cord and laminectomy.

There are a number of the problems that exist in currently available SCS systems that limit the full benefits of dorsal column stimulation from an effectiveness and patient user friendly perspective. One problem is that current SCS systems are limited to only 16 electrodes with a maximum of 16 independent current sources. Another problem is that current SCS systems have complicated trialing methods that involve multiple gadgets and hardware. Another problem is that patients must carry an independent remote control in order to control the IPG in their daily lives.

SUMMARY

Disclosed are the following features included within a spinal cord stimulation system: (1) a recharging system with self alignment, (2) a system for mapping current fields using a completely wireless system, (3) multiple independent electrode stimulation outsource, and (4) IPG control, during trial and permanent implants, through software on generic Smartphone/mobile device and tablet hardware. The SCS system can include multiple electrodes, and multiple, independently programmable, stimulation channels within an implantable pulse generator (IPG) where the channels can provide concurrent, but unique stimulation fields, permitting virtual electrodes to be realized. The SCS system can include a replenishable power source (e.g., rechargeable battery) that may be recharged using transcutaneous power transmissions between antenna coil pairs. An external charger unit, having a rechargeable battery can be used to charge the IPG replenishable power source. A real-time clock can provide an auto-run schedule for daily stimulation. An included bi-directional telemetry link in the system can inform the patient or clinician of the status of the system, including the state of charge of the IPG battery. Other processing circuitry in the IPG allows electrode impedance measurements to be made. Circuitry provided in the external battery charger can provide alignment detection for the coil pairs. A SCS system, as described herein, may be for use during the trial period and the permanent implantation.

The SCS system, as disclosed herein, is superior to existing SCS systems in that the SCS system, as disclosed herein, can provide a stimulus to a selected pair or group of a multiplicity of electrodes, e.g., 32 electrodes, grouped into multiple channels, e.g., 6 channels. In an embodiment, each electrode is able to produce a programmable constant output current of at least 12 mA over a range of output voltages that may go as high as 16 volts. In another embodiment, the implant portion of the SCS system includes a rechargeable power source, e.g., one or more rechargeable batteries. The SCS system described herein requires only an occasional recharge, has an implanted portion smaller than existing implant systems, has a self aligning feature to guide the patient in aligning the charger over the implanted IPG for the most efficient power recharge, has a life of at least 10 years at typical settings, offers a simple connection scheme for detachably connecting a lead system thereto, and is extremely reliable.

In an embodiment, each of the electrodes included within the stimulus channels can deliver up to 12.7 mA of current over the entire range of output voltages, and can be combined with other electrodes to deliver current up to a maximum of 20 mA. Additionally, the SCS system provides the ability to stimulate simultaneously on all available electrodes in the SCS system. That is, in operation, each electrode can be grouped with at least one additional electrode to form one channel. The SCS system allows the activation of electrodes to at least 10 channels. In one embodiment, such grouping is achieved by a low impedance switching matrix that allows any electrode contact or the system case (which may be used as a common, or indifferent, electrode) to be connected to any other electrode. In another embodiment, programmable output current DAC's (digital-to-analog converters) are connected to each electrode node, so that, when enabled, any electrode node can be grouped with any other electrode node that is enabled at the same time, thereby eliminating the need

for a low impedance switching matrix. This advantageous feature allows the clinician to provide unique electrical stimulation fields for each current channel, heretofore unavailable with other "multichannel" stimulation systems (which "multi-channel" stimulation systems are really multiplexed single channel stimulation systems). Moreover, this feature, combined with multicontact electrodes arranged in two or three dimensional arrays, allows "virtual electrodes" to be realized, where a "virtual electrode" comprises an electrode that appears to be at a certain physical location, but in actuality is not physically located at the certain physical location. Rather, the "virtual electrode" results from the vector combination of electrical fields from two or more electrodes that are activated simultaneously.

In embodiments, the SCS system includes an implantable pulse generator (IPG) powered by a rechargeable internal battery, e.g., a rechargeable lithium ion battery providing an output voltage that varies from about 4.1 volts, when fully charged, to about 3.5 volts.

Embodiments are comprised of components previously not provided on SCS systems. The components are comprised of a number of different sub-components, as described herein. The SCS system can be comprised of an permanent implantable IPG, an implantable trial IPG, a wireless dongle, an IPG charger, clinical programmer software, patient programmer software, leads (percutaneous and paddle), lead anchors, lead splitters, lead extensions, and accessories.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** depicts various components that can be included in a spinal cord stimulation system, according to an embodiment, during trial and permanent implantation.

FIG. **2** depicts an exploded view of an implantable pulse generator (IPG) assembly, according to an embodiment.

FIG. **3** depicts a feedthrough assembly of an implantable pulse generator (IPG) assembly, according to an embodiment.

FIG. **4** depicts a lead contact system of an implantable pulse generator (IPG) assembly, according to an embodiment.

FIG. **5** depicts a lead contact assembly of an implantable pulse generator (IPG) assembly, according to an embodiment.

FIG. **6** depicts a head unit assembly of an implantable pulse generator (IPG) assembly, according to an embodiment.

FIG. **7** depicts an RF antenna of an implantable pulse generator (IPG) assembly, according to an embodiment.

FIG. **8** depicts a percutaneous lead, according to an embodiment.

FIG. **9** depicts a paddle lead, according to an embodiment.

FIG. **10** depicts a lead extension, according to an embodiment.

FIG. **11** depicts a lead splitter, according to an embodiment.

FIG. **12** depicts a sleeve anchor, according to an embodiment.

FIG. **13** depicts a mechanical locking anchor, according to an embodiment.

FIG. **14** illustrates communication via a wireless dongle with a tablet/clinician programmer and smartphone/mobile/patient programmer during trial and/or permanent implantation, according to an embodiment.

FIG. **15** depicts a Tuohy needle, according to an embodiment.

FIG. **16** depicts a stylet, according to an embodiment.

FIG. **17** depicts a passing elevator, according to an embodiment.

FIG. **18** depicts a tunneling tool, according to an embodiment.

FIG. **19** depicts a torque wrench, according to an embodiment.

DETAILED DESCRIPTION

Implantable Pulse Generator (IPG)

FIG. **1** illustrates various components that can be included in a SCS system for the trial and the permanent installation periods. The spinal cord stimulator (SCS) **100** is an implantable device used to deliver electrical pulse therapy to the spinal cord in order to treat chronic pain. The implantable components of the system consist of an Implantable Pulse Generator (IPG) **102** and a multitude of stimulation electrodes **130**. The IPG **102** is implanted subcutaneously, no more than 30 mm deep in an area that is comfortable for the patient while the stimulation electrodes **130** are implanted directly in the epidural space. The electrodes **130** are wired to the IPG **102** via leads **140**, **141** which keep the stimulation pulses isolated from each other in order to deliver the correct therapy to each individual electrode **130**.

The therapy delivered consists of electrical pulses with controlled current amplitude ranging from +12.7 to −12.7 mA (current range 0-25.4 mA). These pulses can be programmed in both length and frequency from 10 μS to 2000 μS and 0.5 Hz to 1200 Hz. At any given moment, the sum of the currents sourced from the anodic electrodes **130** must equal the sum of the currents sunk by the cathodic electrodes **130**. In addition, each individual pulse is bi-phasic, meaning that once the initial pulse finishes another pulse of opposite amplitude is generated after a set holdoff period. The electrodes **130** may be grouped into stimulation sets in order to deliver the pulses over a wider area or to target specific areas, but the sum of the currents being sourced at any one given time may not exceed 20 mA. A user can also program different stimulation sets (up to eight) with different parameters in order to target different areas with different therapies.

FIG. **2** depicts an exploded view of an IPG **102**. The IPG **102** consists of two major active components **104**, **106**, a battery **108**, antenna **110**, some support circuitry, and a multitude of output capacitors **112**. The first of the major active components is the microcontroller **104** transceiver **104**. It is responsible for receiving, decoding, and execution both commands and requests from the external remote. If necessary it passes these commands or requests onto the second major component, the ASIC **106**. The ASIC **106** receives the digital data from the microcontroller **104** and performs the entire signal processing to generate the signals necessary for stimulation. These signals are then passed onto the stimulation electrodes **130** in the epidural space.

The ASIC **106** is comprised of a digital section and an analog section. The digital section is divided into multiple sections including; Timing Generators, Arbitration Control, Pulse Burst Conditioner, and Electrode Logic. The analog section receives the incoming pulses from the digital section and amplifies them in order to deliver the correct therapy. There are also a multitude of digital register memory elements that each section utilizes, both digital and analog.

The digital elements in the ASIC **106** are all made up of standard subsets of digital logic including logic gates, timers, counters, registers, comparators, flip-flips, and decoders. These elements are ideal for processing the stimulation pulses as all of them can function extremely fast—orders of magni-

tudes faster than the required pulse width. The elements all function at one single voltage, usually 5.0, 3.3, 2.5, or 1.8 volts.

The timing generators are the base of each of the stimulation sets. It generates the actual rising and falling edge triggers for each phase of the bi-phasic pulse. It accomplishes this by taking the incoming clock that is fed from the microcontroller **104** and feeding it into a counter. For the purpose of this discussion, assume the counter simply counts these rising clock edges infinitely. The output of the counter is fed into six different comparators. The comparators other input is connected to specific registers that are programmed by the microcontroller **104**. When the count equals the value stored in the register, the comparator asserts a positive signal.

The first comparator is connected to the SET signal of a SR flip flop. The SR flip flop stays positive until the RESET signal is asserted, which the second comparator is connected to. The output of the SR flip flop is the first phase of the bi-phasic pulse. Its rising & falling edges are values stored in the registers and programmed by the microcontroller **104**. The third and fourth comparators & registers work in exactly the same way to produce the second phase of the bi-phasic pulse using the second SR flip flop.

The fifth comparator is connected the RESET of the final SR-Flip flop in the timing generator. This flip flop is SET by the first comparator, which is the rising edge of the first pulse. The RESET is then triggered by the value the microprocessor programmed into the register connected to the comparator. This allows for a 'holdoff' period after the falling edge of the second pulse. The output of this third SR flip flop can be thought of as an envelope of the biphasic pulses indicating when this particular timing generator is active.

The final comparator of the system is once again connected to a register that stores the frequency values from the microprocessor. Essentially when the count reaches this value it triggers the comparator which is fed back to the counter to reset it to zero and beginning the entire pulse generation cycle again. The ASIC **106** may contain many of these timing generators as each can control anywhere from two to all of the electrodes **130** connected to the IPG **102** at a time. However, when there is more than one timing generator and multiple channels have been actively programmed then there needs to be a mechanism for suppressing a second channel from turning on when another is already active.

The next circuit block contained in the IPG **102** is the arbitrator. The arbitrator functions by looking at each of the timing generators' envelope signals and makes sure only one can be active at a time. If a second tries to activate then the arbitrator suppresses that signal.

The arbitrator accomplishes this by bringing each of the channel envelope signals into a rising edge detection circuit. Once one is triggered it is fed into the SET pin of an SR flip flop. The output of this SR-flip flop is fed into all of the other rising edge detectors in order to suppress them from triggering. The channel envelope signal is also fed into a falling-edge detector which is then fed into the RESET of the same SR flip flop. The output of the SR flip flops are then connected to switches whose outputs are all tied together that turn on/off that channels particular biphasic pulse train. Therefore, the output of this circuit element is a single bi-phasic pulse train and a signal designating which timing generator that particular pulse train is sourced from. Essentially, the circuit looks for a channel to go active. Once it finds one it suppresses all others until that channel becomes inactive.

The next section of the circuit works very similarly to the timing generators to create a high speed burst pulse train that is then combined with the stimulation pulse train to create a bursted bi-phasic pulse train if desired.

It accomplishes this by taking the incoming clock that is fed from the microcontroller **104** and feeding it into a counter. The counter can count these rising clock edges infinitely. The counter is only active during a single phase of the bi-phasic signal and begins counting as soon as the rising edge is detected. The output of the counter is fed into a comparator, along with a microcontroller-programmed register, whose output is connected to the reset pin on the counter. Therefore, this counter will simply count to a programmed value and reset. This programmed value is the burst frequency.

The output of the comparator is then fed into an edge detection circuit and then a flip flop that combines it with the actual stimulation pulse train to create a single phase bursted stimulation pulse. The entire circuit is duplicated for the second phase of the signal resulting in the desired bursted bi-phasic pulse train. The stimulation signal is now handed over to the electrode logic stage.

The electrode logic conditions and directs the bi-phasic signals to the analog section of the ASIC **106**. At this point, the bi-phasic signals contain all of the pertinent timing information, but none of the required amplitude information. The incoming signals include the bi-phasic pulse train and another signal designating which timing generator the current active train came from. Each electrode logic cell has a register for each timing generator that stores this particular electrode's **130** amplitude values for that timing generator. The electrode logic cell uses the designation signal to determine which register to pull the amplitude values from, e.g. if the third timing generator is passed through the arbitration circuit then the electrode logic would read the value from the third register.

Once the value is pulled from the register, it goes through a series of logic gates. The gates first determine that the electrode **130** should be active. If not, no further action is taken and the analog section of the electrode output is not activated, thereby saving precious battery **108** power. Next, a determination is made if the particular electrode **130** is an anode or cathode. If the electrode is deemed to be an anode, the electrode logic passes the amplitude information and the biphasic signal to the positive current (digital to analog converter) DAC in the analog section of the ASIC **106**. If the electrode is deemed to be a cathode, the electrode logic passes the amplitude information and the biphasic signal to the negative current DAC in the analog section of the ASIC **106**. The electrode logic circuit must make these decisions for each phase of the bi-phasic signal as every electrode **130** will switch between being an anode and a cathode.

The analog elements in the ASIC **106** are uniquely designed in order to produce the desired signals. The basis of analog IC design is the field effect transistor (FET) and the type of high current multiple output design required in SCS **100** means that the bulk of the silicon in the ASIC **106** will be dedicated to the analog section.

The signals from the electrode output are fed into each current DAC when that specific electrode **130** should be activated. Each electrode **130** has a positive and a negative current DAC, triggered by the electrode logic and both are never active at the same time. The job of each current DAC is, when activated, to take the digital value representing a stimulation current amplitude and produce an analog representation of this value to be fed into the output stage. This circuit forms half of the barrier between the digital and analog sections of the ASIC **106**.

The digital section of the ASIC **106** is built upon a technology that only allows small voltages to exist. In moving to

the analog section, the output of the current DAC (which is a low level analog signal) must be amplified to a higher voltage for use in the analog section. The circuit that performs this task is called a power level shifter. Because this circuit is built upon two different manufacturing technologies and requires high precision analog circuits built upon a digital base, it can be difficult to implement.

Once the voltages have been converted for usage in the analog portion of the ASIC **106** the voltages are passed on to the output current stages. There are two current sources per electrode output. One will source a positive current and one will sink a negative current, but both will never be active simultaneously. The current sources themselves are made up of analog elements similar to a Howland current source. There is an input stage, and an amplification stage with feedback through a sensing component to maintain the constant current. The input stage takes the analog voltage values from the power level shifter and produces an output pulse designated for the amplifier. The amplifier then creates the pulses of varying voltages but constant current flow. The sources are capable of sourcing or sinking up to 12.7 mA at 0.1 mA resolution into a load of up to 1.2 k Ohms. This translates into range of 15 volts, which will vary depending on the load in order to keep the current constant.

The microcontroller **104** to ASIC **106** interface is designed to be as simple as possible with minimal bus 'chatter' in order to save battery **108** life. The ASIC **106** can be a collection of registers programmed via a standard I^2C or SPI bus. Since the ASIC **106** is handling all the power management, there will also be a power good (PG) line between the two chips **104**, **106** in order to let the microcontroller **104** know when it is safe to power up. The ASIC **106** will also need to use a pin on the microcontroller **104** in order to generate a hardware interrupt in case anything goes awry in the ASIC **106**. The final connection is the time base for all of the stimulation circuitry. The ASIC **106** will require two clocks, one for its internal digital circuitry which will be fed directly from the microcontroller **104** clock output, and one to base all stimulation off of which will need to be synthesized by the microcontroller **104** and fed to the ASIC **106**. All commands and requests to the ASIC **106** will be made over the I^2C or SPI bus and will involve simply reading a register address or writing to a register. Even when the ASIC **106** generates a hardware interrupt, it will be the responsibility of the microcontroller **104** to poll the ASIC **106** and determine the cause of the interrupt.

The wireless interface is based upon the FCCs MedRadio standard operating in the 402-405 Mhz range utilizing up to 10 channels for telemetry. The protocol implemented is chosen to minimize transmission and maximize battery **108** life. All processing will take place on the user remote/programmer and the only data transmitted is exactly what will be used in the microcontroller **104** to ASIC **106** bus. That is, all of the wireless packets will contain necessary overhead information along with only a register address, data to store in the register, and a command byte instructing the microcontroller **104** what to do with the data. The overhead section of the wireless protocol will contain synchronization bits, start bytes, an address which is synchronized with the IPG's **102** serial number, and a CRC byte to assure proper transmission. The packet length is kept as small as possible in order to maintain battery **108** life. Since the IPG **102** cannot listen for packets all the time due to battery **108** life, it cycles on for a duty cycle of less than 0.05% of the time. This time value can be kept small as long as the data packets are also small. The user commands needed to run the system are executed by the entire system using flows.

The IPG **102** uses an implantable grade Li ion battery **108** with 215 mAHr with zero volt technology. The voltage of the battery **108** at full capacity is 4.1 V and it supplies current only until it is drained up to 3.3 V which is considered as 100% discharged. The remaining capacity of the battery **108** can be estimated at any time by measuring the voltage across the terminals. The maximum charge rate is 107.5 mA. A Constant Current, Constant Voltage (CCCV) type of regulation can be applied for faster charging of the battery **108**.

The internal secondary coil **109** is made up of 30 turns of 30 AWG copper magnet wires. The ID, OD, and the thickness of the coil are 30, 32, and 2 mm, respectively. Inductance L**2** is measured to be 58 uH, a 80 nF capacitor is connected to it to make a series resonance tank at 74 kHz frequency. In the art of induction charging, two types of rectifiers are considered to convert the induced AC into usable DC, either a bridge full wave rectifier or a voltage doubler full wave rectifier. To obtain a higher voltage, the voltage double full wave rectifier is used in this application. The rectifier is built with high speed Schottky diodes to improve its function at high frequencies of the order 100 kH. A Zener diode and also a 5V voltage regulator are used for regulation. This circuit will be able to induce AC voltage, rectify to DC, regulate to 5V and supply 100 mA current to power management IC that charges the internal battery **108** by CCCV regulation.

The regulated 5V 100 mA output from the resonance tank is fed to, for example, a Power Management Integrated Circuit (PMIC) MCP73843. This particular chip was specially designed by Microchip to charge a Li ion battery **108** to 4.1 V by CCCV regulation. The fast charge current can be regulated by changing a resistor; it is set to threshold current of 96 mA in the example circuit. The chip charges the battery **108** to 4.1V as long as the current received is more than 96 mA. However, if the supply current drops below 96 mA, it stops to charge the battery **108** until the supply is higher than 96 again. For various practical reasons, if the distance between the coils increases, the internal secondary coil **109** receives lesser current than the regulated value, and instead of charging the battery **108** slowly, it pauses the charging completely until it receives more than 96 mA. It is understood to those with skill in the art that other power management chips can be used and the power management chip is not limited to the PMIC MCP738432 chip.

All the functions of the IPG **102** are controlled from outside using a hand held remote controller specially designed for this device. Along with the remote control, an additional control is desirable to operate the IPG **102** if the remote control was lost or damaged. For this purpose a Hall effect based magnet switch was incorporated to either turn ON or turn OFF the IPG **102** using an external piece of magnet. Magnet switch acts as a master control for the IPG **102** to turn on or off. A south pole of sufficient strength turns the output on and a north pole of sufficient strength turns the output off. The output is latched so that the switch continues to hold the state even after the magnet is removed from its vicinity.

The IPG **102** is an active medical implant that generates an electrical signal that stimulates the spinal cord. The signal is carried through a stimulation lead **140** that plugs directly into the IPG **102**. The IPG **102** recharges wirelessly through an induction coil **109**, and communicates via RF radio antenna **110** to change stimulation parameters. The IPG **102** is implanted up to 3 cm below the surface of the skin and can be fixed to the fascia by passing two sutures through holes in the epoxy header **114**. The leads **140** are electrically connected to the IPG **102** through a lead contact system **116**, a cylindrical spring-based contact system with inter-contact silicone seals. The leads **140** are secured to the IPG **102** with a set screw **117**

that actuates within locking housing **118**. Set screw compression on the lead's **140** fixation contact can be governed by a disposable torque wrench. The wireless recharging is achieved by aligning the exterior induction coil on the charger with the internal induction coil **109** within the IPG **102**. The RF antenna within the remote's dongle **200** communicates with the RF antenna **110** in the IPG's **102** epoxy header **114**. FIG. **2** illustrates an exploded view of the IPG **102** assembly.

The IPG **102** is an assembly of a hermetic titanium (6Al-4V) casing **120** which houses the battery **108**, circuitry **104**, **106**, and charging coil **109**. The IPG **102** further includes an epoxy header **114** (see FIG. **6**), which houses the lead contact assembly **116**, locking housing **118**, and RF antenna **110** (see FIGS. **6** and **7**). The internal electronics are connected to the components within the epoxy head through a hermetic feedthrough **122**, as shown in FIG. **3**. The feedthrough **122** is a titanium (6Al-4V) flange with an alumina window and gold trimming. Within the alumina window are thirty-four platinum-iridium (90-10) pins that interface internally with a direct solder to the circuit board, and externally with a series of platinum iridium wires laser-welded to the antenna **110** and lead contacts **126**. The IPG **102** interfaces with 32 electrical contacts **126**, which are arranged in four rows of eight contacts **126**. Thirty two of the feedthrough's **122** pins **124** interface with the contacts **126**, while two interface with the antenna **110**, one to the ground plane and one to the antenna **110** feed.

FIGS. **4** and **5** depict a lead contact system **115** and assembly **116**, respectively. The lead contacts **126** consist of an MP35N housing **128** with a platinum-iridium 90-10 spring **129**. Each contact **126** is separated by a silicone seal **127**. At the proximal end of each stack of 8 contacts **126** is a titanium (6Al-4V) cap **125** which acts as a stop for the lead **140**. At the distal end is a titanium (6Al-4V) set screw **119** and block **118** for lead fixation. At the lead entrance point is a silicone tube **123** which provides strain relief as the lead **140** exits the head unit **114**, and above the set screw **119** another silicone tube **131** with a small internal canal allows the torque wrench to enter but does not allow the set screw **119** to back out. In addition to the contacts **126** and antenna **110**, the header **114** also contains a radiopaque titanium (6Al-4V) tag **132** which allows for identification of the device under fluoroscopy. The overmold of the header **114** is Epotek 301, a two-part, biocompatible epoxy. FIGS. **4**, **5**, **6**, and **7** depict illustrations of lead contact system **115**, lead contact assembly **116**, head unit assembly **114**, and RF antenna **110**, respectively.

Internal to the titanium (6Al-4V) case **120** are the circuit board **105**, battery **108**, charging coil **109**, and internal plastic support frame. The circuit board **105** can be a multi-layered FR-4 board with copper traces and solder mask coating. Non-solder masked areas of the board can be electroless nickel immersion gold. The implantable battery **108**, all surface mount components, ASIC **106**, microcontroller **104**, charging coil **109**, and feedthrough **122** will be soldered to the circuit board **105**. The plastic frame, made of either polycarbonate or ABS, will maintain the battery's **108** position and provide a snug fit between the circuitry **105** and case **120** to prevent movement. The charging coil **109** is a wound coated copper.

Leads

The percutaneous stimulation leads **140**, as depicted in FIG. **8**, are a fully implantable electrical medical accessory to be used in conjunction with the implantable SCS **100**. The primary function of the lead is to carry electrical signals from the IPG **102** to the target stimulation area on the spinal cord. Percutaneous stimulation leads **140** provide circumferential stimulation. The percutaneous stimulation leads **140** provide a robust, flexible, and bio-compatible electric connection between the IPG **102** and stimulation area. The leads **140** are surgically implanted through a spinal needle, or epidural needle, and are driven through the spinal canal using a steering stylet that passes through the center of the lead **140**. The leads **140** are secured mechanically to the patient using either an anchor or a suture passed through tissue and tied around the body of the lead **140**. The leads **140** are secured at the proximal end with a set-screw **119** on the IPG **102** which applies radial pressure to a blank contact on the distal end of the proximal contacts.

The percutaneous stimulation leads **140** consist of a combination of implantable materials. Stimulation electrodes **130** at the distal end and electrical contacts at the proximal end are made of a 90-10 platinum-iridium alloy. This alloy is utilized for its bio-compatibility and electrical conductivity. The electrodes **130** are geometrically cylindrical. The polymeric body of the lead **140** is polyurethane, chosen for its bio-compatibility, flexibility, and high lubricity to decrease friction while being passed through tissue. The polyurethane tubing has a multi-lumen cross section, with one center lumen **142** and eight outer lumens **144**. The center lumen **142** acts as a canal to contain the steering stylet during implantation, while the outer lumens **144** provide electrical and mechanical separation between the wires **146** that carry stimulation from the proximal contacts to distal electrodes **130**. These wires **146** are a bundle of MP35N strands with a 28% silver core. The wires **146** are individually coated with ethylene tetrafluoroethylene (ETFE), to provide an additional non-conductive barrier. The wires **146** are laser welded to the contacts and electrodes **130**, creating an electrical connection between respective contacts on the proximal and distal ends. The leads **140** employ a platinum-iridium plug **148**, molded into the distal tip of the center lumen **142** to prevent the tip of the steering stylet from puncturing the distal tip of the lead **140**. Leads **140** are available in a variety of 4 and 8 electrode **130** configurations. These leads **140** have 4 and 8 proximal contacts (+1 fixation contact), respectively. Configurations vary by electrode **130** number, electrode **130** spacing, electrode **130** length, and overall lead **140** length.

The paddle stimulation leads **141**, as depicted in FIG. **9**, are a fully implantable electrical medical accessory to be used in conjunction with the implantable SCS **100**. The primary function of the paddle lead **141** is to carry electrical signals from the IPG **102** to the target stimulation area on the spinal cord. The paddle leads **141** provide urn-direction stimulation across a 2-dimensional array of electrodes **130**, allowing for greater precision in targeting stimulation zones. The paddle stimulation leads **141** provide a robust, flexible, and biocompatible electric connection between the IPG **102** and stimulation area. The leads **141** are surgically implanted through a small incision, usually in conjunction with a laminotomy or laminectomy, and are positioned using forceps or a similar surgical tool. The leads **141** are secured mechanically to the patient using either an anchor or a suture passed through tissue and tied around the body of the lead **141**. The leads **141** are secured at the proximal end with a set-screw on the IPG **102** which applies radial pressure to a fixation contact on the distal end of the proximal contacts.

The paddle stimulation leads **141** consist of a combination of implantable materials. Stimulation electrodes **130** at the distal end and electrical contacts at the proximal end are made of a 90-10 platinum-iridium alloy utilized for its bio-compatibility and electrical conductivity. The polymeric body of the lead **141** is polyurethane, chosen for its bio-compatibility, flexibility, and high lubricity to decrease friction while being passed through tissue. The polyurethane tubing has a multi-lumen cross section, with one center lumen **142** and eight

outer lumens **144**. The center lumen **142** acts as a canal to contain the steering stylet during implantation, while the outer lumens **144** provide electrical and mechanical separation between the wires **146** that carry stimulation from the proximal contacts to distal electrodes **130**. These wires **146** are a bundle of MP35N strands with a 28% silver core. The wires **146** are individually coated with ethylene tetrafluoroethylene (ETFE), to provide an additional non-conductive barrier. At the distal tip of the paddle leads **141** is a 2-dimensional array of flat rectangular electrodes **130** molded into a flat silicone body **149**. In an embodiment, one side of the rectangular electrodes **130** is exposed, providing uni-directional stimulation. The wires **146** are laser welded to the contacts and electrodes **130**, creating an electrical connection between respective contacts on the proximal and distal ends. Also molded into the distal silicone paddle is a polyester mesh **147** adding stability to the molded body **149** while improving aesthetics by covering wire **146** routing. The number of individual 8-contact leads **141** used for each paddle **141** is governed by the number of electrodes **130**. Electrodes **130** per paddle **141** range from 8 to 32, split into between one and four proximal lead **141** ends. Each proximal lead **141** has 8 contacts (+1 fixation contact). Configurations vary by electrode **130** number, electrode **130** spacing, electrode length, and overall lead length.

The lead extensions **150**, as depicted in FIG. **10**, are a fully implantable electrical medical accessory to be used in conjunction with the implantable SCS **100** and either percutaneous **140** or paddle **141** leads. The primary function of the lead extension **150** is to increase the overall length of the lead **140**, **141** by carrying electrical signals from the IPG **102** to the proximal end of the stimulation lead **140**, **141**. This extends the overall range of the lead **140**, **141** in cases where the length of the provided leads **140**, **141** are insufficient. The lead extensions **150** provide a robust, flexible, and bio-compatible electric connection between the IPG **102** and proximal end of the stimulation lead **140**, **141**. The extensions **150** may be secured mechanically to the patient using either an anchor or a suture passed through tissue and tied around the body of the extension **150**. Extensions **150** are secured at the proximal end with a set-screw **119** on the IPG **102** which applies radial pressure to a fixation contact on the distal end of the proximal contacts of the extension **150**. The stimulation lead **140**, **141** is secured to the extension **150** in a similar fashion, using a set screw **152** inside the molded tip of extension **150** to apply a radial pressure to the fixation contact at the proximal end of the stimulation lead **140**, **141**.

The lead extension **150** consists of a combination of implantable materials. At the distal tip of the extension **150** is a 1×8 array of implantable electrical contacts **154**, each consisting of MP35 housing **128** and 90-10 platinum-iridium spring. A silicone seal **127** separates each of the housings **128**. At the proximal end of the contacts is a titanium (6Al4V) cap which acts as a stop for the lead, and at the distal tip, a titanium (6Al4V) block and set screw **152** for lead fixation. The electrical contacts at the proximal end are made of a 90-10 platinum-iridium alloy utilized for its bio-compatibility and electrical conductivity. The polymeric body **156** of the lead **150** is polyurethane, chosen for its bio-compatibility, flexibility, and high lubricity to decrease friction while being passed through tissue. The polyurethane tubing **158** has a multi-lumen cross section, with one center lumen **142** and eight outer lumens **144**. The center lumen **142** acts as a canal to contain the steering stylet during implantation, while the outer lumens **144** provide electrical and mechanical separation between the wires **146** that carry stimulation from the proximal contacts to distal electrodes. These wires **146** are a bundle of MP35N strands with a 28% silver core. The wires **146** are individually coated with ethylene tetrafluoroethylene (ETFE), to provide an additional non-conductive barrier. Each lead extension **150** has 8 proximal cylindrical contacts (+1 fixation contact).

The lead splitter **160**, as depicted in FIG. **11**, is a fully implantable electrical medical accessory which is used in conjunction with the SCS **100** and typically a pair of 4-contact percutaneous leads **140**. The primary function of the lead splitter **160** is to split a single lead **140** of eight contacts into a pair of 4 contact leads **140**. The splitter **160** carries electrical signals from the IPG **102** to the proximal end of two 4-contact percutaneous stimulation leads **140**. This allows the surgeon access to more stimulation areas by increasing the number of stimulation leads **140** available. The lead splitter **160** provides a robust, flexible, and bio-compatible electrical connection between the IPG **102** and proximal ends of the stimulation leads **140**. The splitters **160** may be secured mechanically to the patient using either an anchor or a suture passed through tissue and tied around the body of the splitter **160**. Splitters **160** are secured at the proximal end with a set-screw **119** on the IPG **102** which applies radial pressure to a fixation contact on the distal end of the proximal contacts of the splitter **160**. The stimulation leads **140** are secured to the splitter **160** in a similar fashion, using a pair of set screws inside the molded tip of splitter **160** to apply a radial pressure to the fixation contact at the proximal end of each stimulation lead **140**.

The lead splitter **160** consists of a combination of implantable materials. At the distal tip of the splitter **160** is a 2×4 array of implantable electrical contacts **162**, with each contact **162** consisting of MP35 housing **128** and 90-10 platinum-iridium spring. A silicone seal **127** separates each of the housings **128**. At the proximal end of each row of contacts **162** is a titanium (6Al4V) cap which acts as a stop for the lead, and at the distal tip, a titanium (6Al4V) block and set screw for lead fixation. The electrical contacts at the proximal end of the splitter **160** are made of a 90-10 platinum-iridium alloy utilized for its bio-compatibility and electrical conductivity. The polymeric body **164** of the lead **160** is polyurethane, chosen for its bio-compatibility, flexibility, and high lubricity to decrease friction while being passed through tissue. The polyurethane tubing **166** has a multi-lumen cross section, with one center lumen **142** and eight outer lumens **144**. The center lumen **142** acts as a canal to contain the steering stylet during implantation, while the outer lumens **144** provide electrical and mechanical separation between the wires **146** that carry stimulation from the proximal contacts to distal electrodes **130**. These wires **146** are a bundle of MP35N strands with a 28% silver core. The wires **146** are individually coated with ethylene tetrafluoroethylene (ETFE), to provide an additional non-conductive barrier. Each lead splitter **160** has 8 proximal contacts (+1 fixation contact), and 2 rows of 4 contacts **162** at the distal end.

Anchors

The lead anchor **170**, as depicted in FIGS. **12** and **13**, is a fully implantable electrical medical accessory which is used in conjunction with both percutaneous **140** and paddle **141** stimulation leads. The primary function of the lead anchor **170** is to prevent migration of the distal tip of the lead **140**, **141** by mechanically locking the lead **140**, **141** to the tissue. There are currently two types of anchors **170**, a simple sleeve **171**, depicted in FIG. **12**, and a locking mechanism **172**, depicted in FIG. **13**, and each has a slightly different interface. For the simple sleeve type anchor **171**, the lead **140**, **141** is passed through the center thru-hole **174** of the anchor **171**, and then a suture is passed around the outside of the anchor **171** and tightened to secure the lead **140**, **141** within the anchor **171**. The anchor **171** can then be sutured to the fascia. The locking

anchor **172** uses a set screw **176** for locking purposes, and a bi-directional disposable torque wrench for locking and unlocking. Tactile and audible feedback is provided for both locking and unlocking.

Both anchors **171**, **172** can be molded from implant-grade silicone, but the locking anchor **172** uses an internal titanium assembly for locking. The 3-part mechanism is made of a housing **175**, a locking set screw **176**, and a blocking set screw **177** to prevent the locking set screw from back out. All three components can be titanium (6Al4V). The bi-directional torque wrench can have a plastic body and stainless steel hex shaft.

Wireless Dongle

The wireless dongle **200** is the hardware connection to a smartphone/mobile **202** or tablet **204** that allows communication between the trial generator **107** or IPG **102** and the smartphone/mobile device **202** or tablet **204**, as illustrated in FIG. **14**. During the trial or permanent implant phases, the wireless dongle **200** is connected to the tablet **204** through the tablet **204** specific connection pins and the clinician programmer software on the tablet **204** is used to control the stimulation parameters. The commands from the clinician programmer software are transferred to the wireless dongle **200** which is then transferred from the wireless dongle **200** using RF signals to the trial generator **107** or the IPG **102**. Once the parameters on the clinician programmers have been set, the parameters are saved on the tablet **204** and can be transferred to the patient programmer software on the smartphone/mobile device **202**. The wireless dongle **200** is composed of an antenna, a microcontroller (having the same specifications as the IPG **102** and trial generator **107**), and a pin connector to connect with the smartphone/mobile device **202** and the tablet **204**.

Charger

The IPG **102** has a rechargeable lithium ion battery **108** to power its activities. An external induction type charger **210** (FIG. **1**) wirelessly recharges the included battery **108** inside the IPG **102**. The charger **210** is packaged into a housing and consists of a rechargeable battery, a primary coil of wire and a printed circuit board (PCB) containing the electronics. In operation, charger **210** produces a magnetic field and induces voltage into the secondary coil **109** in the IPG **102**. The induced voltage is then rectified and used to charge the battery **108** inside the IPG **102**. To maximize the coupling between the coils, both internal and external coils are combined with capacitors to make them resonate at a particular common frequency. The coil acting as an inductor L forms an LC resonance tank. The charger uses a Class-E amplifier topology to produce the alternating current in the primary coil around the resonant frequency. The charger **210** features include, but are not limited to:

- Charge IPG **102** wirelessly
- Charge up to a maximum depth of 30 mm
- Integrated alignment sensor indicates alignment between the charger and IPG **102** resulting in higher power transfer efficiency
- Alignment sensor provides audible and visual feedback to the user
- Compact and Portable

A protected type of cylindrical Li ion battery is used as the charger **210** battery. A Class-E power amplifier topology is a much used type of amplifier for induction chargers, especially for implantable electronic medical devices. Due to the Class-E power amplifier's relatively high theoretical efficiency it is often used for devices where high efficiency power transfer is necessary. A 0.1 ohm high wattage resistor is used in series to sense the current through this circuit.

The primary coil L**1** is made by 60 turns of Litz wire type 100/44-100 strands of 44 AWG each. The Litz wire solves the problem of skin effect and keeps its impedance low at high frequencies. Inductance of this coil was initially set at 181 uH, but backing it with a Ferrite plate increases the inductance to 229.7 uH. The attached ferrite plate focuses the produced magnetic field towards the direction of the implant. Such a setup helps the secondary coil receive more magnetic fields and aids it to induce higher power.

When the switch is ON, the resonance is at frequency

$$f = \frac{1}{2\pi\sqrt{L1C2}}$$

When the switch is OFF, it shifts to

$$f = \frac{1}{2\pi\sqrt{L1\dfrac{C1C2}{C1+C2}}}$$

In a continuous operation the resonance frequency will be in the range

$$\frac{1}{2\pi\sqrt{L1C2}} < f < \frac{1}{2\pi\sqrt{L1\dfrac{C1C2}{C1+C2}}}.$$

To make the ON and OFF resonance frequencies closer, a relatively larger value of C1 can be chosen by a simple criteria as follows

C1=nC2; a value of n=4 was used in the example above; in most cases 3<n<10.

The voltages in these Class-E amplifiers typically go up to the order of 300 VAC. Capacitors selected must be able to withstand these high voltages, sustain high currents and still maintain low Effective Series Resistance (ESR). Higher ESRs result in unnecessary power losses in the form of heat. The circuit is connected to the battery through an inductor which acts as a choke. The choke helps to smoothen the supply to the circuit. The N Channel MOSFET acts as a switch in this Class-E power amplifier. A FET with low ON resistance and with high drain current I_d is desirable.

In summary, the circuit is able to recharge the IPG **102** battery **108** from 0 to 100% in approximately two hours forty-five minutes with distance between the coils being 29 mm. The primary coil and the Class-E amplifier draws DC current of 0.866 A to achieve this task. To improve the efficiency of the circuit, a feedback closed loop control is implemented to reduce the losses. The losses are minimum when the MOSFET is switched ON and when the voltage on its drain side is close to zero.

The controller takes the outputs from operational amplifiers, checks if the outputs meet the criteria, then triggers the driver to switch ON the MOSFET for the next cycle. The controller can use a delay timer, an OR gate and a 555 timer in monostable configuration to condition the signal for driver. When the device is switched ON, the circuit will not function right away as there is no active feedback loop. The feedback becomes active when the circuit starts to function. To provide an active feedback loop, an initial external trigger is applied to jump start the system.

Alignment Sensor

The efficiency of the power transfer between the external charger **210** and the internal IPG **102** will be maximum only when the charger **210** and IPG **102** are properly aligned. An alignment sensor is provided to ensure proper alignment as part of the external circuit design and is based on the principle of reflected impedance. When the external coil is brought closer to the internal coil, the impedance of both circuits change. The sensing is based on measuring the reflected impedance and testing whether it crosses the threshold. A beeper provides an audible feedback to the patient and a LED provides visual feedback.

When the impedance of the circuit changes, the current passing through it also changes. A high power 0.1 ohm resistor can be used in the series of the circuit to monitor the change in current. The voltage drop across the resistor is amplified 40 times and then compared to a fixed threshold value using an operational amplifier voltage comparator. The output is fed to a timer chip which in turn activates the beeper and LED to provide feedback to the user.

The circuit can sense the alignment up to a distance of approximately 30 mm. The current fluctuation in the circuit depends on more factors than reflected impedance alone and the circuit is sensitive to other parameters of the circuit as well. To reduce the sensitivity related to other parameters, one option is to eliminate interference of all the other factors and improve the functionality of the reflected impedance sensor—which is very challenging to implement within the limited space available for circuitry. Another option is to use a dedicated sensor chip to measure the reflected impedance.

A second design uses sensors designed for proximity detector or metal detectors for alignment sensing. Chips designed to detect metal bodies by the effect of Eddy currents on the HF losses of a coil can be used for this application. The TDE0160 is an example of such a chip.

The external charger is designed to work at 75 to 80 kHz, whereas the proximity sensor was designed for 1 MHz. The sensor circuit is designed to be compatible with the rest of the external and is fine tuned to detect the internal IPG **102** from a distance of approximately 30 mm.

Programmer

The Clinician Programmer is an application that is installed on a tablet **204**. It is used by the clinician to set the stimulation parameters on the trial generator **107** or IPG **102** during trial and permanent implantation in the operating room. The clinician programmer is capable of saving multiple settings for multiple patients and can be used to adjust the stimulation parameters outside of the operations room. It is capable of changing the stimulation parameters though the RF wireless dongle **200** when the trial generator **107** or IPG **102** which has been implanted in the patient is within the RF range. In addition, it is also capable of setting or changing the stimulation parameters on the trial generator **107** and/or the IPG **102** through the internet when both the tablet **204** and the Patient Programmers on a smartphone/mobile device **202** both have access to the internet.

The Patient Programmer is an application that is installed on a smartphone/mobile device **202**. It is used by the patient to set the stimulation parameters on the trial generator **107** or IPG **102** after trial and permanent implantation outside the operating room. The clinician programmer is capable of saving multiple settings for multiple patients and can be transferred to the Patient Programmer wirelessly when the Clinician Programmer tablet **204** and the Patient Programmer smartphone/mobile device **202** are within wireless range such as Bluetooth from each other. In the scenario where the Clinician Programmer tablet **204** and the Patient Programmer smartphone/mobile device **202** are out of wireless range from each other, the data can be transferred through the internet where both devices **202**, **204** have wireless access such as Wi-Fi. The Patient Programmer is capable of changing the stimulation parameters on the trial generator **107** or IPG **102** though the RF wireless dongle **200** when the trial generator **107** or IPG implanted in the patient is within the RF range.

Tuohy Needle

The tuohy needle **240**, as depicted in FIG. **15**, is used in conjunction with a saline-loaded syringe for loss-of-resistance needle placement, and percutaneous stimulation leads **140**, for lead **140** placement into the spinal canal. The tuohy epidural needle **240** is inserted slowly into the spinal canal using a loss-of-resistance technique to gauge needle **240** depth. Once inserted to the appropriate depth, the percutaneous stimulation lead **140** is passed through the needle **240** and into the spinal canal.

The epidural needle **240** is a non-coring 14G stainless steel spinal needle **240** and will be available in lengths of 5" (127 mm) and 6" (152.4). The distal tip **242** of the needle **240** has a slight curve to direct the stimulation lead **140** into the spinal canal. The proximal end **246** is a standard Leur-Lock connection **248**.

Stylet

The stylet **250**, as depicted in FIG. **16**, is used to drive the tip of a percutaneous stimulation lead **140** to the desired stimulation zone by adding rigidity and steerability. The stylet **250** wire **252** passes through the center lumen **142** of the percutaneous lead **140** and stops at the blocking plug at the distal tip of the lead **140**. The tip of the stylet **250** comes with both straight and curved tips. A small handle **254** is used at the proximal end of the stylet **250** to rotate the stylet **250** within the center lumen **142** to assist with driving. This handle **254** can be removed and reattached allowing anchors **170** to pass over the lead **140** while the stylet **250** is still in place. The stylet **250** wire **252** is a PTFE coated stainless steel wire and the handle **254** is plastic.

Passing Elevator

The passing elevator **260**, as depicted in FIG. **17**, is used prior to paddle lead **141** placement to clear out tissue in the spinal canal and help the surgeon size the lead to the anatomy. The passing elevator **260** provides a flexible paddle-shaped tip **262** to clear the spinal canal of obstructions. The flexible tip is attached to a surgical handle **264**.

The passing elevator **260** is a one-piece disposable plastic instrument made of a flexible high strength material with high lubricity. The flexibility allows the instrument to easily conform to the angle of the spinal canal and the lubricity allows the instrument to easily pass through tissue.

Tunneling Tool

The tunneling tool **270**, as depicted in FIG. **18**, is used to provide a subcutaneous canal to pass stimulation leads **140** from the entrance point into the spinal canal to the IPG implantation site. The tunneling tool **270** is a long skewer-shaped tool with a ringlet handle **272** at the proximal end **274**. The tool **270** is covered by a plastic sheath **276** with a tapered tip **278** which allows the tool **270** to easily pass through tissue. Once the IPG **102** implantation zone is bridge to the lead **140** entrance point into the spinal canal, the inner core **275** is removed, leaving the sheath **276** behind. The leads **140** can then be passed through the sheath **276** to the IPG **102** implantation site. The tunneling tool **270** is often bent to assist in steering through the tissue.

The tunneling tool **270** is made of a 304 stainless steel core with a fluorinated ethylene propylene (FEP) sheath **276**. The

304 stainless steel is used for its strength and ductility during bending, and the sheath **276** is used for its strength and lubricity.

Torque Wrench

The torque wrench **280**, as depicted in FIG. **19**, is used in conjunction with the IPG **102**, lead extension **150** and lead splitter **160** to tighten the internal set screw **119**, which provides a radial force against the fixation contact of the stimulation leads **140**, **141**, preventing the leads **140**, **141** from detaching. The torque wrench **280** is also used to lock and unlock the anchor **170**. The torque wrench **280** is a small, disposable, medical instrument that is used in every SCS **100** case. The torque wrench **280** provides audible and tactile feedback to the surgeon that the lead **140**, **141** is secured to the IPG **102**, extension **150**, or splitter **160**, or that the anchor **170** is in the locked or unlocked position.

The torque wrench **280** is a 0.9 mm stainless steel hex shaft **282** assembled with a plastic body **284**. The wrench's **280** torque rating is bi-directional, primarily to provide feedback that the anchor **170** is either locked or unlocked. The torque rating allows firm fixation of the set screws **119**, **152** against the stimulation leads **140**, **141** without over-tightening.

Trial Patch

The trial patch is used in conjunction with the trialing pulse generator **107** to provide a clean, ergonomic protective cover of the stimulation lead **140**, **141** entrance point in the spinal canal. The patch is also intended to cover and contain the trial generator **107**. The patch is a large, adhesive bandage that is applied to the patient post-operatively during the trialing stage. The patch completely covers the leads **140**, **141** and generator **107**, and fixates to the patient with anti-microbial adhesive.

The patch is a watertight, 150 mm×250 mm anti-microbial adhesive patch. The watertight patch allows patients to shower during the trialing period, and the anti-microbial adhesive decreases the risk of infection. The patch will be made of polyethylene, silicone, urethane, acrylate, and rayon.

Magnetic Switch

The magnetic switch is a magnet the size of a coin that, when placed near the IPG **102**, can switch it on or off. The direction the magnet is facing the IPG **102** determines if the magnetic switch is switching the IPG **102** on or off.

We claim:

1. An implantable pulse generator comprising:

a casing having an epoxy header;

a circuit board housed in the casing comprising:

a microcontroller;

a single application specific integrated circuit (ASIC) in communication with the microcontroller, the single ASIC having a combined analog and digital sections, wherein the analog section further comprises at least one pair of digital to analog convertors (DAC) wherein one of the pair is a positive current DAC and the other of the pair is a negative current DAC, and wherein the ASIC generates stimulation signals;

a plurality of output capacitors;

a power management chip in electrical communication with the microcontroller; and

support circuitry;

an implantable grade lithium ion rechargeable battery housed in the casing and in electrical communication with the circuit board;

a charging coil in electrical communication with the rechargeable battery;

a RF antenna housed in the epoxy header; and

a wireless interface.

2. The implantable pulse generator of claim **1**, the ASIC digital section comprising:

a plurality of digital register memory elements in electrical communication with the microprocessor;

a plurality of timing generators in electrical communication with the microprocessor and in receipt of a clock signal, the clock signal fed to a counter, an output of the counter fed to a first input of each of a plurality of comparators and a second input of each of the plurality of comparators is in electrical communication with one of the plurality of digital register memory elements;

a plurality of flip-flops wherein each flip-flop is in electrical communication with an output of a predetermined combination of the plurality of comparators and wherein the plurality of flip-flops output phases of a bi-phasic pulse;

an arbitration control in electrical communication with the plurality of flip-flops and outputting a bi-phasic pulse train and wherein the arbitration control analyzes the timing generator envelope signals and permits only one signal to be active at a time; and

a pulse burst conditioner in electrical communication with the arbitration control wherein the pulse burst conditioner outputs a bursted bi-phasic pulse train and the signal is fed to a plurality of electrode logic circuits to condition and direct the bursted bi-phasic pulse train signals to the at least one pair of DACs in the analog section of the ASIC.

3. The implantable pulse generator of claim **2**, wherein the at least one positive current DAC and the at least one negative current DAC are configured to not be active concurrently.

4. The implantable pulse generator of claim **2**, the analog section of the ASIC further comprising:

a power level shifter to amplify an output of the positive or negative current DAC to a higher voltage;

an output current stage having an input stage and an amplification stage with feedback, wherein the input stage is in electrical communication with the output of the power level shifter and the output of input stage is fed to an input of the amplification stage wherein the feedback uses a sensing component to maintain a constant current.

5. The implantable pulse generator of claim **4**, wherein the amplified signals are pulses of varying voltages but constant current flow.

6. The implantable pulse generator of claim **2**, wherein the timing generator generates rising and falling edge triggers for each phase of the bi-phasic pulse.

7. The implantable pulse generator of claim **2**, wherein the counter signal is based on a microcontroller clock signal, and the register signal is based on registers programmed by the microcontroller such that when the count of the counter equals a value stored in the register, the comparator outputs a positive signal.

8. The implantable pulse generator of claim **1**, further comprising a magnet switch activatable by an external magnet to enable and disable the implantable pulse generator.

9. The implantable pulse generator of claim **1**, further comprising a lead contact system housed in the epoxy header wherein the lead contact system provides connection for up to thirty-two leads.

10. The implantable pulse generator of claim **1**, wherein the lead contact system comprises:

a plurality of locking housings, each locking housing defining an aperture, the aperture configured to accept a silicone tube and the silicone tube configured to accept a

lead, and wherein the locking housing further defines a second aperture configured to accept a compression lead lock mechanism; and

a plurality of lead contacts, each lead contact separated from an adjacent lead contact by a silicone seal, wherein the lead contacts are configured in stacks of up to eight lead contacts and each stack is connected at one end to one locking housing and wherein the lead contacts connect to the feedthrough.

11. The implantable pulse generator of claim **1**, wherein stimulation parameters are input to the implantable pulse generator via the wireless interface.

12. The implantable pulse generator of claim **11**, wherein the inputted stimulation parameters contain overhead information, a register address, data to be stored in the register, and a command byte dictating microprocessor function.

13. The implantable pulse generator of claim **1**, wherein the feedthrough has at least 32 pins.

14. The implantable pulse generator of claim **1**, wherein the implantable pulse generator is configured to deliver stimulus to a plurality of implantable stimulation electrodes wherein the electrodes can be grouped into stimulation sets, and the stimulation sets can be grouped into multiple channels wherein the channels have two or more stimulation sets of electrodes.

15. The implantable pulse generator of claim **14**, wherein at least ten channels are activated by connecting the positive current or negative current DAC to any one of the plurality of electrodes contact or the casing to be connected to any other ones of the plurality of electrodes.

16. The implantable pulse generator of claim **15**, wherein the implantable pulse generator is configured to deliver the bi-phasic electrical pulses to a plurality of implantable stimulation electrodes wherein the electrodes are grouped in stimulation sets, each stimulation set programmable with different stimulation parameters.

17. The implantable pulse generator of claim **16**, wherein the plurality of implantable stimulation electrodes output a programmable constant output current of at least 12.7 mA over a range of output voltages, wherein the output voltages can be as high as 16 volts.

18. The implantable pulse generator of claim **14**, wherein at least ten channels are activated by a low impedance switching matrix allowing any one of the plurality of electrodes contact or the casing to be connected to any other ones of the plurality of electrodes.

19. A method of providing an implantable pulse generator to provide stimulation to a spinal cord comprising:

implanting the implantable pulse generator subcutaneously;

implanting a plurality of implantable stimulation electrodes in the epidural space;

electrically connecting the plurality of implantable stimulation electrodes to the implantable pulse generator via a plurality of implantable leads, wherein the number of implantable leads can be up to 32;

inputting stimulation parameters on a computing device via a clinician programmer application;

communicating the stimulation parameters to the implantable pulse generator via a wireless communication device; and

delivering electrical pulses based on the stimulation parameters to the electrodes,

wherein the implantable pulse generation includes a single application specific integrated circuit (ASIC) in communication with the microcontroller, the single ASIC having a combined analog and digital sections, wherein the analog section further comprises at least one pair of digital to analog convertors (DAC) wherein one of the pair is a positive current DAC and the other of the pair is a negative current DAC, and wherein the ASIC generates stimulation signals.

20. A kit for delivery of stimulation to a spinal cord comprising:

an implantable pulse generator for delivering electrical pulses;

a plurality of implantable stimulation electrodes for implanting in the epidural space;

a plurality of implantable leads for electrically connecting the plurality of implantable stimulation electrodes to the implantable pulse generator;

a clinician programmer application on a computing device for inputting stimulation parameters;

a wireless communications device for communicating the stimulation parameters to the implantable pulse generator from the computing device,

wherein the implantable pulse generation includes a single application specific integrated circuit (ASIC) in communication with the microcontroller, the single ASIC having a combined analog and digital sections, wherein the analog section further comprises at least one pair of digital to analog convertors (DAC) wherein one of the pair is a positive current DAC and the other of the pair is a negative current DAC, and wherein the ASIC generates stimulation signals.

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